

BEST AVAILABLE COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 37697-0039

Applicant(s): William H. HARRIS et al.

Confirmation No.: 8865

Serial No.: 10/040,900

Examiner: Paul B. Prebilic

Filing Date: January 9, 2002

Group Art Unit: 3738

Title: POLYETHYLENE HIP JOINT PROSTHESES WITH EXTENDED RANGE OF MOTION

DECLARATION OF DR. WILLIAM H. HARRIS

I, William H. Harris, do hereby declare as follows:

1. I understand that the claims in the captioned application have been rejected over *Graham et al.* (US 5,549,700) or *Townley et al.* (US 6,096,084) in view of *McKellop et al.* ("McKellop", US 6,165,223). In order to address this rejection, I submitted a declaration, filed on July 6, 2004. It appeared to me that the Examiner has understood my declaration suggesting a "trend in the art to smaller diameter surfaces", but the examiner has not addressed the "disadvantages of using larger diameter surfaces", which were made of conventional UHMWPE, such as used by *Towley*.

2. It appears that the Examiner has misunderstood my previous declaration, and therefore a clarification would be useful in considering (i) the content of the prior art, especially, regarding linear versus volumetric wear, and (ii) that the invention has satisfied a long felt unmet need in the field.

3. Regarding Exhibit I (Elfeck et al., 1998) of my July 6, 2004 declaration, the Examiner quoted that there is "no actual proof" provided in the Exhibit that larger head sizes resulted in higher wear rate. Elfeck et al. (Tab-1) reported that "[a] 32-mm-diameter head has a 45% greater sliding distance than a 22-mm head per cycle; hence as wear is proportional to sliding distance, the wear should be 45% larger per cycle." (see page 294, first column, last paragraph). Elfeck et al. further stated that "[the] most important conclusion to be drawn from this study is the detrimental effect of the large

U.S. Serial No. 10/040,900

femoral head size. This accelerates the volumetric wear rate, therefore reducing the components' expected life. An additional consequence of the 32-mm head is the reduction in polyethylene thickness attainable for a given acetabular outer diameter." (see "Conclusion" on page 295, first paragraph). Thus, Elfeck *et al.* provided sufficient proof that larger head sizes resulted in higher wear rate.

4. Regarding Exhibit II (Livermore *et al.*, 1990) of my July 6, 2004 declaration, the Examiner quoted that the "difference in wear between 28 mm and 32 mm diameter surfaces [] were not statistically significant." The Examiner has not addressed the difference between the liner wear rate and the volumetric wear rate. The phrase "difference in wear between 28 and 32 mm surfaces were not statistically significant" refers to the linear penetration, not to the volumetric wear. Because the diameter of the 32 mm head exceeds that of the 28 mm head, the greatest volumetric wear and mean wear rate (in contrast with linear penetration rate) were greater for the 32 mm heads than the 28 mm heads. Volumetric wear is the key, not linear penetration. See Livermore *et al.* (1990) (Tab-2) for example, page 523, Table I, which shows head sizes of 22 mm, 28 mm, and 32 mm generated 1.35 mm, 0.85 mm, and 1.10 mm linear wear, respectively. Whereas, the volumetric wear for the head sizes 22 mm, 28 mm, and 32 mm were 513 mm³, 521 mm³, and 911 mm³, respectively. In short, 32 mm heads generated far greater volumetric wear than 22 mm and 28 mm heads against conventional polyethylene.

5. The critical issue as far as the failure of total hip replacements concerned is the volumetric wear. Volumetric wear is responsible for the total number of particles generated that elicits the adverse biological response that leads to the bone resorption (periprosthetic osteolysis). It is the periprosthetic osteolysis or bone resorption that causes re-operations and leads to loss of fixation of the components. Thus, it is clear that larger heads in the ranges used at the time generated greater volumetric wear, and thereby generated more particles. Data are recorded in the exhibits submitted earlier, see for example:

Schmalzried *et al.* (1993) (Tab-3) demonstrated that "[t]he large diameter of these components [referring to surface replacement] results in a volumetric wear of

U.S. Serial No. 10/040,900

polyethylene that is 4-10 times higher than that produced by a conventional 28 mm diameter bearing for the equivalent number of cycles." (See page 148, Fig. 1 legend).

Clarke *et al.* (1997) (Table 4) also reported an increase in volumetric wear rate with increase in head size. See for example, page 30, Table 4, which shows a range of 23.2 mm³ to 32.8 mm³ volumetric wear rate for head sizes ranging from 22.25 mm to 28 mm, respectively. Clarke *et al.* summarized that the "[v]olumetric wear rate increased with respect to size of femoral head and a linearly increasing relationship of 7-8 per cent/mm was evident with respect to femoral head diameter for both PTFE and polyethylene." (see page 25, Abstract).

6. When larger head diameters (i.e., larger than 32 mm) are used against conventional polyethylene, the wear rate is even greater. This is illustrated convincingly and importantly by the long term report of the outcomes of the total articular replacement arthroplasty (TARA) prosthesis (see Treuting *et al.*, Prohibitive failure rate of the total articular replacement arthroplasty of 510 years. *American Journal of Orthopedics*, 1997:114-118, Tab-5). Treuting *et al.* used "acetabular component sizes ranged from 56 mm to 62 mm in outer diameter, while femoral component sizes ranged from 45 mm to 55 mm in head diameter" (see for example, page 114, second column, under "Materials and Methods") and reported an "overall clinical failure rate [of] 89% (55/62 hips)" (see for example, page 115, right column, under "Results"). Treuting *et al.* conclude that the "factors associated with increased polyethylene wear" include "large diameter of the bearing", and state that "the volumetric wear rate of hip resurfacing components is 4-10 times higher than that of a conventional 28-mm hip bearing." (see page 117, right column last paragraph).

7. Regarding Exhibit IV (Mikawa *et al.* 1997) of my July 6, 2004 declaration, the Examiner has alleged that there is "provided no actual data." Please note that Exhibit IV informed the field that "higher wear rate" occurred, and thus summarized data and results of the study that is responsible for the knowledge of the field. Data in a descriptive format or in a tabular data format represents the same finding, and thus illustrates the view of the field at the time.

U.S. Serial No. 10/040,900

Hirakawa *et al.* studied the relationship between three different femoral head sizes (26, 28, and 32 mm) and the characteristics of wear debris in the adjacent tissues. Hirakawa *et al.* reported that the "[l]arge femoral head diameter (32 mm) was found to correlate significantly with large particle size (diameter and surface area, $p < 0.05$), high tissue concentration of particles (particle volume/gram of tissue, $p < 0.01$), and high rate of particle production (particles volume/month, $p < 0.05$)." The quantitative assays conducted by Hirakawa *et al.* reconfirms that "higher volumetric wear [is] associated with 32 mm femoral head components."

8. There was a direct relationship between the volume of wear produced and the size of the head. Large heads produce a greater volume of wear. As submitted with my previous declaration, Charnley, who invented total hip replacement surgery, was forced to go to smaller and smaller head sizes despite the fact that his original proposed head size was 45 mm in diameter. Charnley was forced to do this because he found that the wear for the larger head sizes was excessive. This is well documented in his book (John Charnley, 1979, *Low Friction Arthroplasty of the Hip: Theory and Practice*, Springer-Verlag, Berlin, Heidelberg, New York, 1979. Pages 3-15, (Tab-6)). See for example, Charnley describes "loading of a small-diameter ball can prevent 'third body' abrasion" (on page 6, right column, last paragraph), "small-diameter femoral head demanded by the theory of low frictional torque" (on page 13, left column, first paragraph), "general trend [] for designs of metal-to-plastic total hip to be moving towards the smaller ranges of femoral head (32, 28 and 25 mm)" (on page 14, right column, first paragraph)

In sum, Charnley experienced the fact that large heads produce a greater volume of wear when he introduced Teflon type plastics. Charnley also observed this wear when switched to the conventional UHMWPE. The observation has subsequently been confirmed by a wide number of studies. For example, Livamore, *et al.* (Tab-2) disclose that "[t]he greatest volumetric wear and mean rate of volumetric wear were seen with thirty-two-millimeter components... who studied the effect of femoral head size on wear of acetabular component made of conventional polyethylene (See page 518, Abstract).

U.S. Serial No. 10/040,900

9. In summary, the two dominant observations from the above publications are: (i) increasing head size increases the volumetric wear, which leads to adverse biological consequences; and (ii) an even greater increase in the wear rate occurs if the femoral head is greater than 32 mm in diameter. The art cited by the Examiner shows that prior art approaches with large head diameters were failure, which is reinforced by McKellop's exclusive focus on heads having diameter of less than 32 mm. Therefore, McKellop teaches away from using large head sizes. Hence, there is no motivation in McKellop to use its cross-linked materials for large head prosthesis, such as those greater than 32 mm.

10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2/17/05
Date

William H. Harris
William H. Harris

List of Exhibits:

Tab No.	Reference
Tab-1	Elfeck <i>et al.</i> 1998.
Tab-2	Livermore <i>et al.</i> 1990.
Tab-3	Schmalzried <i>et al.</i> 1999.
Tab-4	Clarke <i>et al.</i> 1997.
Tab-5	Treuting <i>et al.</i> 1997.
Tab-6	Charnley, J. 1979.

Wear in Retrieved Acetabular Components

Effect of Femoral Head Radius and Patient Parameters

Alistair P. D. Elfick, MSc, Richard M. Hall, PhD, Ian M. Pinder, FRCS,
and Anthony Unsworth, FEng

Abstract: Forty-seven explanted Porous Coated Anatomic (PCA, Howmedica, Rutherford, NJ) cementless acetabular components were acquired at revision surgery. All the components articulated against CoCrMo femoral heads of 32-mm diameter. The penetration depth and angle were measured using the shadowgraph technique. The wear volume was then calculated using Kabo's formula. Using weighted linear regression analysis, the mean penetration rate and mean volumetric wear rate were calculated to be 0.23 (SE, 0.03) mm³/y and 96 (SE, 13) mm³/y, respectively. The creep component was not found to be significantly different from zero. The clinical wear factor, k_{clinical} , for this cohort was also calculated using linear regression analysis but with the assumption that creep was zero. The value found, $k_{\text{clinical}} = 1.93$ (SE, 0.29) $\times 10^{-6}$ mm³/N-m, was similar to those in previous studies involving cemented joints with a 22-mm femoral head diameter. The similar k_{clinical} values of these substantially different joint types suggest that the high volumetric wear rate for the PCA joint can be attributed entirely to its larger head size and the younger, more active, patient profile. Fixation technique and metal backing seem not to influence the rate of wear. **Key words:** total hip arthroplasty, explanted, wear, cementless.

The dominant cause of long-term failure of the Porous Coated Anatomic (PCA, Howmedica, Rutherford, NJ) hip arthroplasty is the loosening, or migration, of the acetabular component. The results achieved with the PCA design were encouraging in the short term, with survivorship rates of 93% at 6 years [1] and 94% of hips attaining a good or excellent Harris rating at 2 years [2]. Survivorship rates of 57% at 8 years, and evidence of acetabular

osteolysis in 36% of hips at 5 years [3], however, demonstrate its poor longevity.

It is generally accepted that the production of particulate debris promotes a foreign-body reaction resulting in resorption of bone and, hence, loosening of the components [4]. The greatest contributor to the amount of debris in the periprosthetic region is wear of the ultrahigh-molecular-weight polyethylene (UHMWPE) socket at the articulating interface. Additional debris may be produced at other interfaces in this modular design, for example, between the liner and backing; however, the volume of debris released from these alternative sources is small in comparison with that from the articulating interface.

The aim of this study was to assess the wear of 47 retrieved acetabular components and to evaluate the effect of the femoral head radius, the polyethylene thickness, and patient parameters.

From the Centre for Biomedical Engineering, School of Engineering, University of Durham, Durham, United Kingdom.

Supported by the Health Executive-Northern and Yorkshire Office Research and Design Directorate and Arthritis and Rheumatism Council Grant U0505.

Reprint requests: Alistair P. D. Elfick, MSc Centre for Biomedical Engineering, School of Engineering, University of Durham, Durham DH1 3LE, UK.

Copyright © 1998 by Churchill Livingstone®
0883-5403/1303-0007\$3.00/0

Materials and Methods

The PCA system is a cementless design relying on the ingrowth of bone into a porous coating for long-term fixation. In early examples of this prosthesis, the liner and backing were supplied as 1 piece and had a simple locking method comprising a single peg at the pole and a tab at the rim to stop rotation about this pole. Later versions incorporated a snaplock mechanism located at the rim and became truly modular. Forty-seven acetabular components were retrieved at revision; 27 were of the 1-piece design and the rest were of the snaplock type. All were coupled with 32-mm-diameter CoCrMo femoral heads. The explanted components were cleaned in a formaldehyde-based solution, and excess bone ingrowth was removed.

The thickness of the UHMWPE has been cited as an important parameter in the performance of the acetabular component [5]; however, the liners of snaplock design were not of constant polyethylene cross-section, and subsequently no single value of wall thickness could be ascribed to each. A ranking for both designs in terms of minimum wall thickness at implantation could be achieved and is detailed in Table 1.

The penetration depth, ΔP , and angle, β , of the wear track into the acetabular liners were measured using a shadowgraph technique [6]. The changes in the internal volume of the bore, ΔV , were calculated using the formula previously presented by Kabo et al. [7]. Those liners that had visual evidence of wear and/or creep but volume changes of insufficient

magnitude to be measured on the shadowgraph instrument were assigned a penetration depth of 0.05 mm, which was equal to the resolution of the apparatus. The change in bore volume of these liners was calculated using a simple linear formula [6].

Mean penetration rates were calculated using regression analysis with a model of the form

$$(1) \quad \Delta P = m\Delta T + c$$

where ΔP is the penetration depth, ΔT is the implant period, and m and c are constants. Given that experimental evidence indicates that the creep component is constant after a relatively short period [8], then the gradient, m , of the function is equal to the penetration wear rate, $\Delta P/\Delta T$. The regression constant, c , may incorporate changes in the internal bore volume or the penetration depth resulting from creep. Mean volumetric wear rate was calculated in a similar manner.

The clinical wear factor, k_{clinical} , is a development of the fundamental wear equation, which states that wear volume is proportional to load and sliding distance. To be applicable to the clinical situation the load is the joint reaction force, a function of patient weight, and the sliding distance becomes a combination of the number of wear cycles and femoral head radius. The clinical wear factor is the constant of proportionality and may be deduced from simplification of the wear equation produced by Dowson and Wallbridge [9]:

$$(2) \quad \Delta V = k_{\text{clinical}} (2.376NWr) + C$$

where N is an estimate of the number of cycles to which the joint has been subjected during its life, r is the radius of the femoral head, and W is patient weight. The number of cycles is calculated using an empirical formula derived by Wallbridge and Dowson [10] relating age to activity:

$$(3) \quad N = 0.5 (A_r - A_p) \times [6.58 - 0.032(A_r + A_p)] \times 10^6$$

Here, A_p is the patient age at primary surgery, and A_r , the age at revision surgery. This formula was based on data gained from normal subjects and therefore it may vary from the level of activity achieved by patients; however, Wallbridge and Dowson [10] warn against the assumption that patients are less active than normal subjects. The mean clinical wear factor was calculated, using regression analysis, in the manner described by Hall et al. [11]. Clinical wear factors of individual sockets were

calculate was negl

Analys the STA Corporat rates of F weightin sis to ma also inco resolutio between and indi using no trend an value of fected by

Clinical

Clinica trievied j taken in 16 were osteoarti nosed in hip in fractured femoral l

Revisio ing evid lytic lesio were dor

Table 1. Ranking in Terms of Minimum Ultrahigh-molecular-weight Polyethylene (UHMWPE) Thickness*

Description	Approximate Minimum UHMWPE Thickness (mm)	Rank
Snaplock, 46/49-mm backing	1.8	1
—	—	2
One-piece, 46-mm backing	4.5	3
Snaplock, 52/55-mm backing	5.0	4
One-piece, 49-mm backing	5.5	5
—	—	6
—	—	7
One-piece, 52-mm backing	7.0	8
Snaplock, 58/61-mm backing	8.0	9
—	—	10
One-piece, 55-mm backing	8.5	11
One-piece, 58-mm backing	10.0	12
Snaplock, 64/67-mm backing	11.0	13

*Note that the ranks 2, 6, 7, and 10 are reserved for other head/backing combinations not applicable to this study.

calculated with the assumption that the creep, C , was negligible.

Analysis was undertaken, for the most part, using the STATA 4.0 statistical software package (Stata Corporation, Texas). In determining k_{clinical} and the rates of penetration and volumetric wear, a suitable weighting had to be applied in the regression analysis to maintain a constant variance. The weighting also incorporated a factor to take into account the resolution of the shadowgraph instrument. Trends between the liner thickness, locking mechanism, and individual clinical wear factors were analyzed using nonparametric trend analysis. Nonparametric trend analysis is reasonably robust to changes in value of the ranking values and, hence, is unaffected by the absence of cups of certain ranks.

Clinical Data

Clinical records were available for all the retrieved joints. The primary procedure was undertaken in 17 cases for rheumatoid arthritis. A further 16 were due to osteoarthritis and 3 to posttraumatic osteoarthritis. Ankylosing spondylitis was diagnosed in 4 cases and congenital dislocation of the hip in 3 others. The remaining cases included fractured neck of the femur and benign tumor of the femoral head.

Revision was undertaken in 31 cases for loosening evidenced by migration of components and/or lytic lesions on the radiograph. A further 9 revisions were done because of pain, and 3, because of gross

wear of the liner. The other cases were revised for sepsis or instability.

Twenty-two of the patients were male. The average weight of the patients, W , was 705 (SD, 155) N. The median age at primary surgery was 44 (range, 15–76) years and the median implant period, ΔT , was 6.2 (range, 0.1–12.3) years.

Results

The mean penetration depth was found to be 1.3 (SE, 0.2) mm, which gave a mean penetration rate of 0.23 (SE, 0.03) mm/y (Fig. 1). The intercept was not found to be significantly different from zero. The mean wear volume was calculated to be 551 (SE, 77) mm³ and a corresponding mean volumetric wear rate of 96 (SE, 13) mm³/y was deduced. The mean total number of cycles to revision was 10.4 (range, 0.03–25.5) $\times 10^6$. The mean clinical wear factor was found to be 1.93 (SE, 0.29) $\times 10^{-6}$ mm³/N-m.

The nonparametric trend analysis showed no correlation between the thickness rank or locking mechanism and the clinical wear factor (Fig. 2).

Discussion

The penetration rates found in this study compare well with those found in other studies on 32-mm-diameter heads [7,12]. These values do not support the notion that there is a reduction in penetration

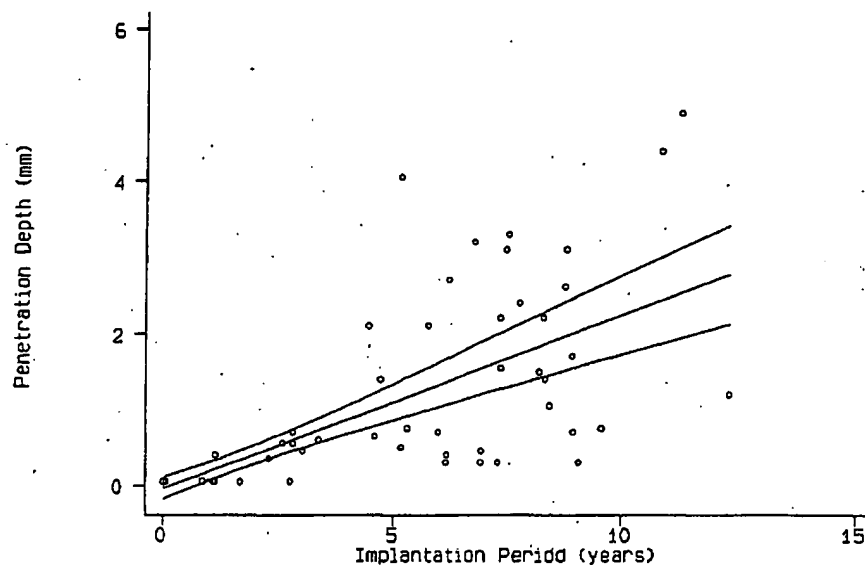


Fig. 1. Determination of the penetration rate using regression analysis. The outer curves are the 95% confidence limits of the prediction. Note that the intercept is approximately equal to zero.

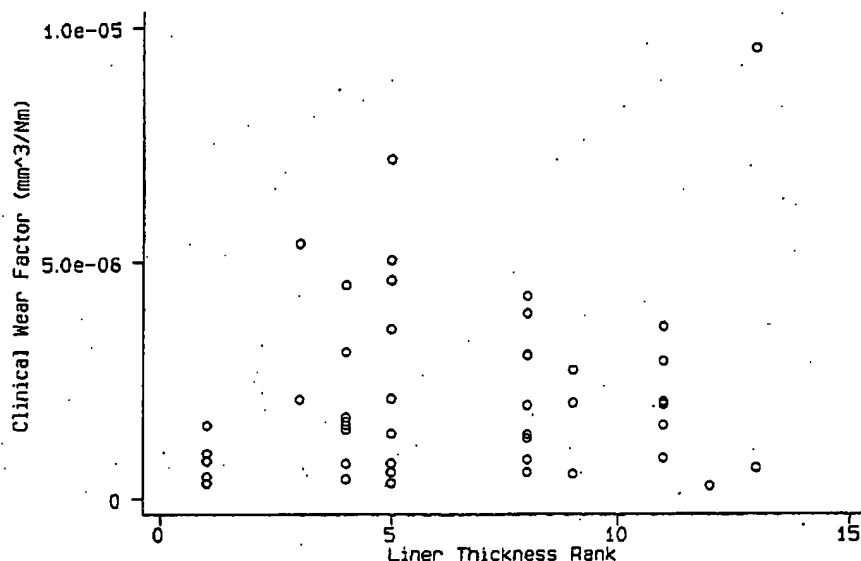


Fig. 2. Variation of the clinical wear factor with liner thickness rank.

with large heads. Indeed, studies involving other head sizes show similar penetration rates; Hernandez et al. reported a penetration rate of 0.22 mm/y with cementless femoral components [13] and Kabo et al. observed a value of 0.23 mm/y [7]; both were for 28-mm-diameter heads. Similarly, for Charnley prostheses (22-mm-diameter heads), Hall et al. [11] and Atkinson et al. [14] both reported linear wear rates of 0.20 mm/y for explant studies.

The similarity in penetration rates may be regarded as coincidental; attention should be focused on the corresponding volumetric wear rates. From Figure 1, it can be seen that the creep component of the penetration is minimal, as evidenced by the zero intercept. Thus, the penetration into the liner is caused mainly by wear. This is reflected in the high mean volumetric wear rate of the PCA, 96 mm³/y. Similarly high volumetric wear rates for 32-mm-diameter heads are reported by Kabo et al. [7]: 88 mm³/y; however, smaller heads show lower rates of wear: 75 mm³/y for 28 mm [7] and 55 mm³/y for 22 mm [11].

The variation in wear rate is in part attributable to the greater sliding distance associated with the larger femoral head sizes. A 32-mm-diameter head has a 45% greater sliding distance than a 22-mm head per cycle; hence, as wear is proportional to sliding distance, the wear should be 45% larger per cycle. The volumetric wear rate we obtained, however, is approximately twice that of studies on 22-mm heads. This further increase may be attributable to the many differences in the prostheses and the patient groups.

At this point, it is advantageous to consider the clinical wear factor. The great benefit of this parameter is the ability to compare the wear performance of prosthetic designs directly despite different patient groupings. Hence, for a given prosthesis design, a heavy, sedentary patient should achieve the same k_{clinical} as a light, active patient. Conversely, if two joint types, say a cemented and an uncemented design both with 32-mm-diameter heads, have the same k_{clinical} , then any difference in the wear rate is attributable to variations in patient activity and weight between the two groups and not the fixation method.

The mean clinical wear factor found in this study of 1.93×10^{-6} mm³/N-m and those for Charnley joints reported by Hall et al. [11] and Atkinson et al. [14] of 2.1×10^{-6} and 1.96×10^{-6} mm³/N-m, respectively, are very similar. We have already established that approximately half the increase in wear rate is attributable to the 32-mm head size over the 22-mm size of the Charnley. The equivalence in clinical wear factor indicates that the remaining increase in wear rate found in our study is attributable to the younger, more active, patient group.

Further, the similarity in clinical wear factors between the PCA and Charnley designs suggests that the wear performance of these two joints is similar; the metal backing and cementless system of the PCA have little effect on the wear, nor does the possibility of cement ingression in the Charnley. Hence, if the PCA was to adopt a 22-mm head and have the same patient profile as the Charnley, then their volumetric wear rates would be comparable.

This is and Ser metal b margin: The k anism, factor i effect o been as et al. [1 liner. T ranking cup wit polyeth mately predisp

The r this stu femoral wear ra pected l head is attainal The p to cont and the Charnk either c wear.

1. Asti coat met Surg
2. Call port Join
3. Owe unc mer
4. Hov part 199

This is in agreement with the findings of Manley and Serekian [15], who observed that the effect of a metal backing is to increase the rate of wear only marginally.

The lack of correlation between the locking mechanism, or thickness rank, and the clinical wear factor indicates that these parameters have little effect on the wear rate; however, these factors have been associated, by Brien et al. [16] and Learmonth et al. [17], with the fracture and dissociation of the liner. This study included 5 liners of thickness ranking 1, which corresponds to a snaplock-type cup with an outer diameter of 46 or 49 mm, giving a polyethylene thickness at implantation of approximately 1.8 mm at its thinnest point. Clearly, this predisposes the design to early mechanical failure.

Conclusion

The most important conclusion to be drawn from this study is the detrimental effect of the large femoral head size. This accelerates the volumetric wear rate, therefore reducing the components' expected life. An additional consequence of the 32-mm head is the reduction in polyethylene thickness attainable for a given acetabular outer diameter.

The presence of the metal backing was not found to contribute substantially to the high wear rate, and the similar clinical wear factors of the PCA and Charnley designs do not suggest any advantage of either cemented or cementless fixation in terms of wear.

References

1. Aston DJ, Saluan P, Stulberg BN et al: The porous-coated anatomic total hip prosthesis: failure of the metal-backed acetabular component. *J Bone Joint Surg* 78A:755, 1996
2. Callaghan JJ, Dysart SH, Savory CG: The uncemented porous-coated anatomic total hip prosthesis. *J Bone Joint Surg* 70A:337, 1988
3. Owen TD, Moran CG, Smith SR, Pinder IM: Results of uncemented porous-coated anatomic total hip replacement. *J Bone Joint Surg* 76B:258, 1994
4. Howie D, Haynes D, Rogers S et al: The response to particulate debris. *Orthop Clin North Am* 24:571, 1993
5. Bartel DL, Burstien AH, Toda MD, Edwards DL: The effect of conformity and plastic thickness on contact stresses in metal-backed plastic implants. *J Biomed Eng* 107:193, 1985
6. Hall RM, Unsworth A, Craig PS et al: Measurement of wear in retrieved acetabular sockets. *Proc Inst Mech Eng* 209H:233, 1995
7. Kabo JM, Gebhard JS, Loren G, Amstutz HC: In vivo wear of polyethylene acetabular components. *J Bone Joint Surg* 75B:254, 1993
8. Elloy M: Simulator testing of joint prostheses: the need for realistic simulator testing. p. 79. In *Proceedings SERC/IMEchE annual expert meeting on the failure of joint prostheses*. Mechanical Engineering Publications, London, 1993
9. Dowson D, Wallbridge NC: Laboratory wear tests and clinical observations of the penetration of femoral heads into acetabular cups in total replacement hip joints: 1. Charnley prostheses with polytetrafluoroethylene acetabular cups. *Wear* 104:225, 1985
10. Wallbridge NC, Dowson D: The walking activity of patients with artificial joints. *Eng Med* 11:95, 1982
11. Hall RM, Unsworth A, Siney P, Wroblewski BM: Wear in retrieved Charnley acetabular sockets. *Proc Inst Mech Eng* 210:197, 1996
12. Devane PA, Bourne RB, Rorabeck CH et al: Measurement of polyethylene wear in metal-backed acetabular cups: 2. Clinical application. *Clin Orthop* 319:317, 1995
13. Hernandez JR, Keating EM, Faris PM et al: Polyethylene wear in uncemented acetabular components. *J Bone Joint Surg* 76B:263, 1994
14. Atkinson JR, Dowson D, Isaac JH, Wroblewski BM: Laboratory wear tests and clinical observations of the penetration of femoral heads into acetabular cups in total replacement hip joints: 3. The measurement of internal volume changes in explanted Charnley sockets after 2-16 years in vivo and the determination of wear factors. *Wear* 104:225, 1985
15. Manley MT, Serekian P: Wear debris: an environmental issue in total joint replacement. *Clin Orthop* 298:137, 1994
16. Brien WW, Salvati EA, Wright TM et al: Dissociation of acetabular components after total hip arthroplasty: report of four cases. *J Bone Joint Surg* 72A:1548, 1990
17. Learmonth ID, Smith EJ, Cunningham JL: The pathogenesis of osteolysis in two different cementless hip replacements. *Proc Inst Mech Eng* 211:59, 1997

der the
param-
-mance
ent pa-
-sis de-
eve the
rsely, if
mented
ave the
rate is
ty and
ixation

study of
y joints
[14] of
vely, are
approx-
-table to
of the
tor indi-
-ound in
e active,

factors
suggests
oints is
-stem of
loes the
arnley.
ead and
sy, then
parable.

Effect of Femoral Head Size on Wear of the Polyethylene Acetabular Component*

BY JOHN LIVERMORE, M.D.†, DUANE ILSTRUP, M.S.†, AND BERNARD MORREY, M.D.†,
ROCHESTER, MINNESOTA

From the Department of Orthopedics and the Section of Biostatistics, Mayo Clinic and Mayo Foundation, Rochester

ABSTRACT: A technique was developed to determine the wear of the acetabular component of a total hip replacement by examination of standardized initial and follow-up radiographs. Three hundred and eighty-five hips were followed for at least 9.5 years after replacement.

The least amount and rate of linear wear were associated with use of a femoral head that had a diameter of twenty-eight millimeters ($p < 0.001$). The greatest amount and mean rate of linear wear occurred with twenty-two-millimeter components, but these differences were not statistically significant. The greatest volumetric wear and mean rate of volumetric wear were seen with thirty-two-millimeter components ($p < 0.001$). A wider radiolucent line in acetabular Zone 1 was associated with use of the thirty-two-millimeter head. The amounts of resorption of the proximal part of the femoral neck and of lysis of the proximal part of the femur both correlated positively with the extent of linear and volumetric wear; this suggests an association between the amount of debris from wear and these changes in the femoral neck and proximal part of the femur.

The mechanical factors affecting wear of the polyethylene in total hip replacement continue to be extensively evaluated in the laboratory, yet no clinical study comparing the effect of femoral head size on the characteristics of wear of high-density polyethylene has been reported, to our knowledge^{1,3,6,10,13,22,24-29,30,32,34,38,42-45,49,54-61,64,65,69,70,72-74,80,81}. Charnley et al.^{11,14} and Dowling et al.²³ evaluated the effect of femoral head size on the rate of wear of polytetrafluoroethylene (Teflon) and determined that the ideal diameter of the femoral head to maximize time to complete penetration is one-half the external diameter of the acetabular component¹⁴. However, they did not take into account concerns about the volume of debris from wear.

The purpose of our long-term clinical study was twofold: to evaluate the effect of femoral head size on the linear and volumetric wear of high-density polyethylene and to correlate the effect of wear with the radiographic appearance of the hip.

* No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. No funds were received in support of this study.

† Mayo Clinic, 200 First Street S. W., Rochester, Minnesota 55905. Please address requests for reprints to Dr. Morrey.

Materials and Methods

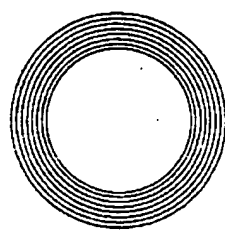
From 1974 to 1976, femoral head components measuring twenty-two, twenty-eight, and thirty-two millimeters were used for joint replacement at the Mayo Clinic. All arthroplasties were performed with use of radiopaque cement. The acetabular components that were used were compression molded and came from a single supplier.

During this period, 385 of 1,964 hip-replacement procedures that were done at the Mayo Clinic satisfied the criteria for entry in this study, which included the availability of a standardized radiograph that had been made, with non-portable equipment, shortly after arthroplasty and of a repeat radiograph made by the same technique at least 9.5 years later. All postoperative and follow-up radiographs were made at the Mayo Clinic, with a tube-to-cassette distance that was standardized in 1969.

The selection of the size of the prosthetic femoral head was based on the preference of the surgeon rather than on random assignment. Of the 385 hips, 227 had the twenty-two-millimeter femoral-head design (Charnley, Howmedica, Rutherford, New Jersey), ninety-eight had the twenty-eight-millimeter design (Trapezoidal-28; Zimmer, Warsaw, Indiana), and sixty had the thirty-two-millimeter design (Müller or Aufranc-Turner; Howmedica). The number of patients in each group was determined to be adequate to distinguish statistical differences among the three groups.

There were no statistically significant differences among groups with regard to the ages of the patients, the preoperative diagnoses, or the previous operative procedures. Men were 60 per cent of the patients who received the thirty-two-millimeter prosthetic head, 41 per cent of those who received the twenty-two-millimeter head, and 48 per cent of those who received the twenty-eight-millimeter head. Proportionately more men had the thirty-two than the twenty-two-millimeter head ($p < 0.03$, chi-square test).

To determine whether there was an association between the patient's weight and the result, we divided the patients into three groups on the basis of body weight: less than sixty-three kilograms, sixty-three to eighty kilograms, and more than eighty kilograms. These weight-ranges were chosen so that there was approximately the same number of patients in each group. The relationships of the preoperative weight of the patient and the size of the prosthetic head to the amount of linear wear, mean rate of wear per year, and volumetric wear were studied in two ways: an analysis of variance was done to study the average wear and size of



Concentric Circle Template



FIG. 1

Demonstration of use of a transparent template with concentric circles, with the radii increasing in increments of one millimeter, for accurate measurement of the prosthetic femoral head. (See the text for a description of use of the template to calculate the factor to correct for magnification.)

the prosthetic head in the three weight-groups, and a multiple linear-regression analysis of wear, head size, and patient weight was calculated. Neither technique revealed a statistically significant difference of the effect of weight on the association of head size and wear.

Linear Wear

Radiographic Measurement

A single observer measured all of the radiographs. Only the anteroposterior radiographs of the pelvis were used for measurement, because the lateral radiographs were often of inadequate quality to allow exact identification of the cement-prosthesis interface. Measurements of the initial post-operative radiographs were done three separate times. The maximum variation by the single observer was 0.1 millimeter. The accuracy of this measurement was further substantiated by the close agreement between the radiographic measurements and the direct measurements from retrieved prostheses, as will be discussed.

The radiographic measurements were made as described by Griffith et al.³³; the cement-prosthesis interface rather than the wire marker was used to identify the proximal border of the polyethylene. Beginning with the radiograph that was made an average of 2.3 months (range, two to four months) after operation, the observer used a transparent overlay with a set of concentric circles and one-millimeter

increments of radial length to locate the center of the femoral head. The precise magnification was calculated from the known dimension of the implant and the size of the femoral

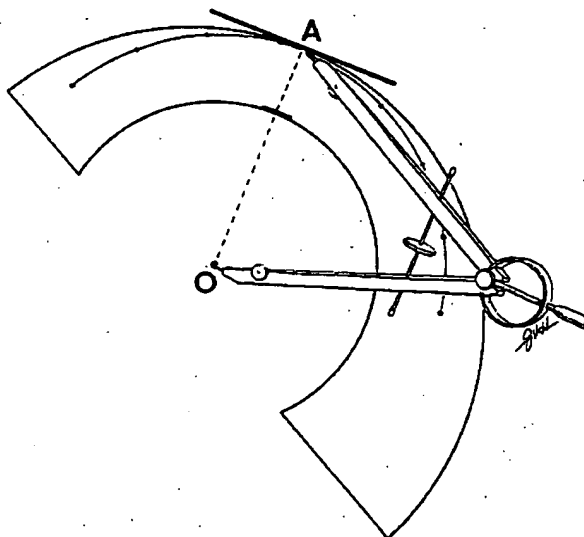


FIG. 2

A compass is used to identify the location of the shortest radius, from the center of the prosthetic femoral head (point O) to a point on the outer surface of the polyethylene acetabular cup (point A).

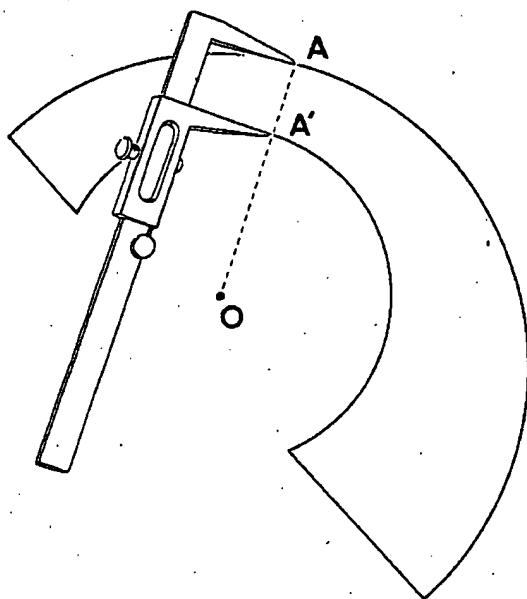


FIG. 3

The distance AA' from the surface of the prosthetic femoral head (point A') along line AO (determined as in Fig. 2) is measured with a caliper to an accuracy of 0.1 millimeter.

head as it appeared radiographically (Fig. 1).

The factor to correct for magnification (that is, the factor by which the observed dimension on the radiograph must be multiplied to obtain the real dimension) is calculated by the formula: correction factor = known diameter of the implant/apparent radiographic diameter.

On the most recent radiograph, a compass was used to locate the point on the acetabular cup-cement interface (point A) that was the shortest distance (AO) from the center of the head of the prosthesis (point O) (Fig. 2). A caliper was used to measure the distance (AA') along this line between the surface of the femoral head (point A') and the acetabular cup-cement interface (point A) to the nearest 0.1 millimeter (Fig. 3). Point A' was considered to be the point of maximum wear and line AA', the line of greatest wear.

The direction of wear was defined relative to a vertical line drawn through the center of the femoral head and perpendicular to a tangent to the ischial tuberosities (Fig. 4). Measurement of the direction from the center of the femoral head to the thinnest portion of the acetabulum, if medial to this vertical line, was defined as a positive angle, θ ; if the direction was lateral to this line, it was defined as a negative angle, α (Fig. 4).

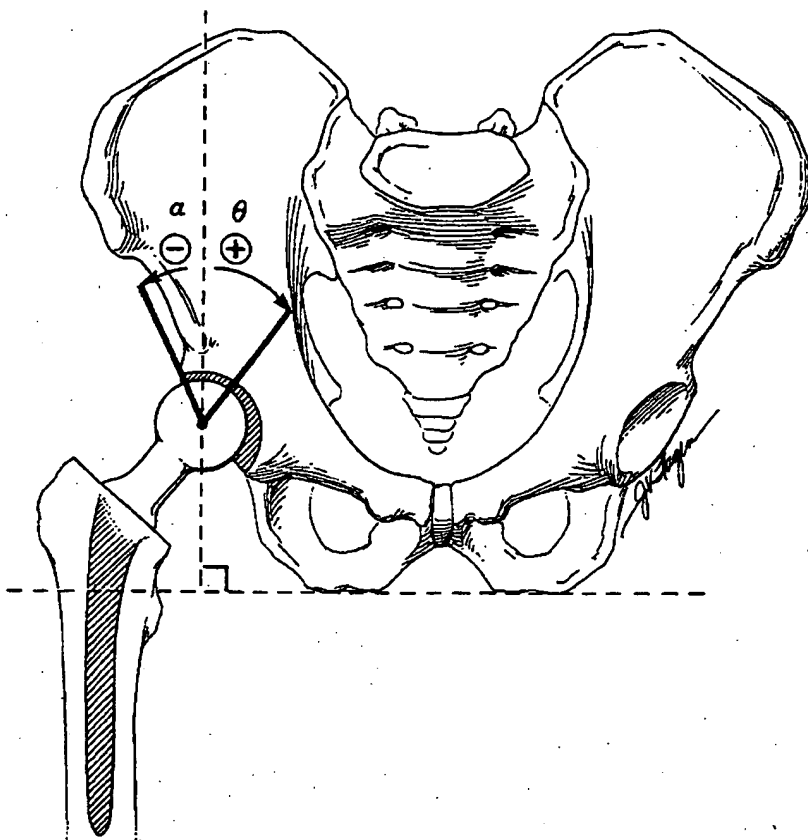


FIG. 4

The direction of greatest penetration is defined in reference to a vertical line passing through the center of the prosthetic femoral head and perpendicular to a line tangent to the ischial tuberosities. Measurement of the direction from the center of the femoral head to the thinnest portion of the acetabulum, if the direction is medial to this vertical line, is defined as a positive angle, θ ; if the direction is lateral to this line, it is defined as a negative angle, α .

On the initial postoperative anteroposterior radiograph of the hip, points A and A' were located in the same position in the acetabular cup as they appeared on the most recent radiograph; if there had been wear, A' would lie inside the outline of the acetabular cup. The initial thickness of the polyethylene cup was measured along the line of greatest wear, AA', from the surface of the head of the prosthesis to point A.

Measurements were corrected for magnification (again,

lateral margin of the acetabular component to the point of maximum wear (distance B) was measured and was corrected for magnification (Fig. 5). The polyethylene thickness (A) at the medial edge of distance B was measured and was corrected for magnification. With use of the anteroposterior and lateral radiographs and the visible landmarks on the retrieved acetabular cups, the orientation of the polyethylene component was determined and marked. The cups were sectioned in the coronal plane. The corrected

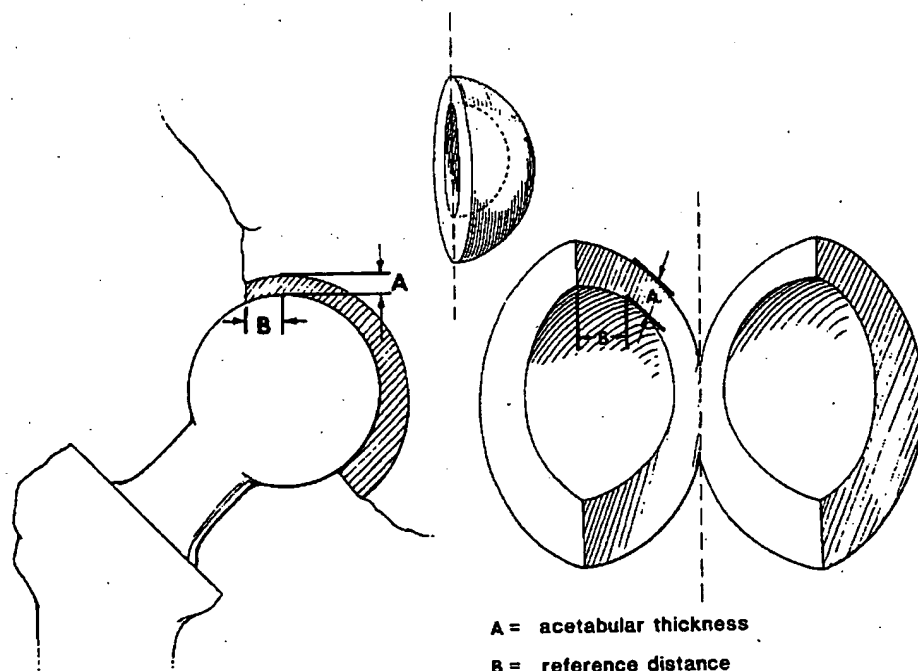


FIG. 5

Diagram showing how the same measurements that are made on radiographs can be made on retrieved acetabular cups to verify the accuracy of the technique of radiographic determination of acetabular wear. The distance from the lateral margin of the cephalad edge of the acetabular component to the point of maximum wear is measured; this is distance B. The thickness of the acetabular cup (distance A) at the point of maximum wear (medial end of the line of distance B) is then measured. These measurements are made on the radiographs and then directly on the retrieved acetabular cups, and, after correction for radiographic magnification, they are compared.

with use of the overlay template of concentric circles over the prosthetic femoral head), and the difference between the corrected values was calculated to determine the distance of linear migration of the femoral head. This technique ensured accurate location and measurement of wear for the three sizes of prosthetic acetabular cup.

Direct Measurement

The reliability of the radiographic technique was confirmed by correlating the measurements with actual measurements of wear from retrieved implants. Since the time of implantation, twelve of the 385 polyethylene acetabular components had been replaced because of aseptic loosening rather than excessive wear. (A review of all 1,964 primary total hip replacements that were done during the period of study revealed that none had been revised because of wear of the polyethylene). Direct measurements of these components were correlated with the measurements on the most recent radiograph before revision. The distance from the

distance, B, was then measured on the sectioned component, and the polyethylene thickness, A, was directly measured at this point with a caliper (Fig. 5). These direct measurements of thickness were compared with the corrected measurements from the radiographs.

Volumes of Wear and Debris from Wear

Charnley et al.¹⁴ found that the femoral head wears through polytetrafluoroethylene acetabular components in a linear path, creating a cylindrical wear-track of the same diameter as that of the femoral head. Dowling²² confirmed this effect in studies of retrieved polyethylene cups of ultra-high molecular weight. These data justify an estimation of the volume of debris from wear (equivalent to volumetric wear) by the formula $v = \pi r^2 w$, in which v is the volume of debris from wear (or volumetric wear), r is the radius of the femoral head, and w is the measured linear migration of the head through the polyethylene. This calculation assumes a uniform pattern of cylindrical wear.



FIG. 6

Anteroposterior radiographs of the same hip, made immediately after arthroplasty with insertion of a thirty-two-millimeter prosthesis and eleven years later. The resorption of the femoral neck (ten millimeters) was rated as moderate, and there was 3.5 millimeters of acetabular wear. There is a three-millimeter radiolucent line in acetabular Zone 1. Note the difference in rotation of the femur between the two radiographs.

Rate of Wear and Statistical Analysis

In previous studies, it was estimated that the wear of twenty-two-millimeter femoral heads averaged 0.1 millimeter per year, with a range of 0.07 to 0.21 millimeter, and that of thirty-two-millimeter heads, 0.2 millimeter per year^{12,13,19,36,82}. With these data, it was calculated that, with a minimum of sixty hips in each of the three groups based on size of the prosthetic femoral head, there was at least a 90 per cent chance that a difference in average wear as low as 0.06 millimeter per year would be detected. It was decided that a smaller sample with well controlled and standardized radiographs provides a more reliable study than a larger sample with radiographs that are produced by different techniques.

The distributions of wear and other continuous variables in the three head-size groups were compared with one-way analysis of variance or one-way analysis of variance by ranks. The Student-Newman-Keuls multiple-comparison method was used to determine the sizes of head that had significantly different means when the analysis of variance was statistically significant.

The associations of wear with other continuous or categorized variables, such as weight of the patient and resorption of the proximal part of the femoral neck, were assessed with the Spearman rank-correlation coefficients. Comparisons of proportions of discrete events were made with the chi-square or Fisher exact test, when appropriate.

Study of the Bone-Cement Interface

As a secondary aspect of this study, the possible radiographic effects of linear wear and calculated volumetric wear — and, therefore, of volume of debris — were assessed. The definitions that were reported by Gruen et al.³⁵

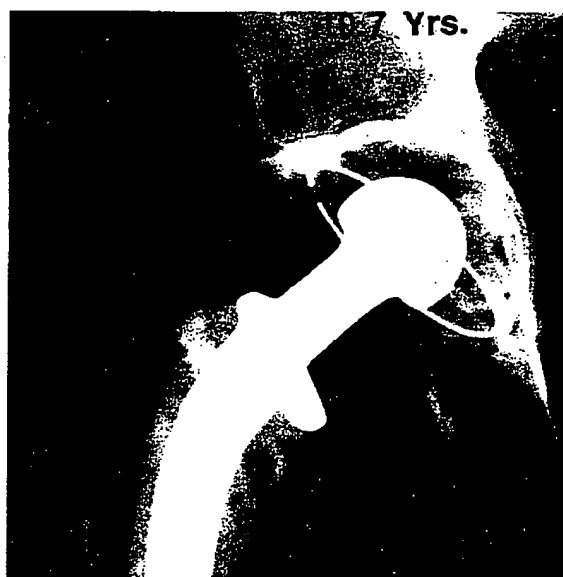


FIG. 7

Anteroposterior radiograph made 10.7 years after implantation, showing a four-millimeter radiolucent line in Zone 7 and acetabular wear of 2.6 millimeters.

for radiolucency around the femoral component and by DeLee and Charnley²¹ for radiolucency around the acetabular component were used. The follow-up radiographs were carefully evaluated for resorption of the proximal part of the femoral neck, osteolysis of the proximal part of the femur, and progressive radiolucent lines at the interface between the bone and cement in the proximal part of the femur³⁵ and in Zone 1 of the acetabulum²¹. Resorption at the proximal part of the femoral neck was quantified for statistical analysis as none, mild (present but less than five

TABLE I
PARAMETERS OF WEAR ACCORDING TO FEMORAL HEAD SIZE*

Head Size (mm)	Linear Wear (mm)	Rate of Linear Wear (mm/yr.)	Volumetric Wear (mm ³)	Rate of Volumetric Wear (mm ³ /yr.)
22	1.35 (0-4.3) \pm 1.0	0.13 (0-0.39) \pm 0.1	513 (0-1617) \pm 393	47.5 (0-147) \pm 36.2
28	0.85† (0-3.7) \pm 0.8	0.08† (0-0.3) \pm 0.07	521 (0-2249) \pm 463	48.4 (0-225) \pm 42.1
32	1.10 (0-3.5) \pm 0.7	0.10 (0-0.32) \pm 0.06	911† (30-2811) \pm 547	84.1† (3-256) \pm 49.8

* Values are given as mean, range (in parentheses), and standard deviation.

† Statistically significant difference ($p < 0.001$).

millimeters), moderate (five to ten millimeters), or severe (greater than ten millimeters) (Fig. 6). The width of any radiolucent line in the proximal femoral (Fig. 7) or acetabular (Fig. 6) bone-cement interface was measured in millimeters, and osteolysis of the proximal part of the femur was recorded simply as present or absent (Fig. 8). These values were then correlated with the calculations for linear and volumetric wear.

Results

Definite wear was observed with all three sizes of head (Table I and Figs. 9 and 10).

Of the twenty-two-millimeter heads, 28 per cent had more than two millimeters of linear wear and 10 per cent, more than three millimeters. The mean amount of linear wear was 1.35 millimeters, with a standard deviation of 1.0 and a range of zero to 4.3 millimeters. The mean rate of linear wear was 0.13 ± 0.1 millimeter (range, zero to 0.39 millimeter) per year. Estimates of volumetric wear revealed

that 77 per cent of the components had less than 800 cubic millimeters of wear and 24 per cent had more than that. The mean volumetric wear was 513 ± 393 cubic millimeters (range, zero to 1,617 cubic millimeters) and the mean rate of volumetric wear was 47.5 cubic millimeters (range, zero to 147 cubic millimeters) per year.

Of the twenty-eight-millimeter heads, 8 per cent had linear wear of more than two millimeters; 2 per cent, more than three millimeters; and none, more than four millimeters. The mean linear wear was 0.85 ± 0.8 millimeter (range, zero to 3.7 millimeters). The mean rate of linear wear was 0.08 ± 0.07 millimeter (range, zero to 0.3 millimeter) per year. Estimates of volumetric wear revealed that 75 per cent of the components had less than 800 cubic millimeters of wear and 24 per cent had more than that. The mean volumetric wear was 521 ± 463 cubic millimeters (range, zero to 2,249 cubic millimeters). The mean rate of volumetric wear was 48.4 ± 42.1 cubic millimeters (range, zero to 225 cubic millimeters) per year.

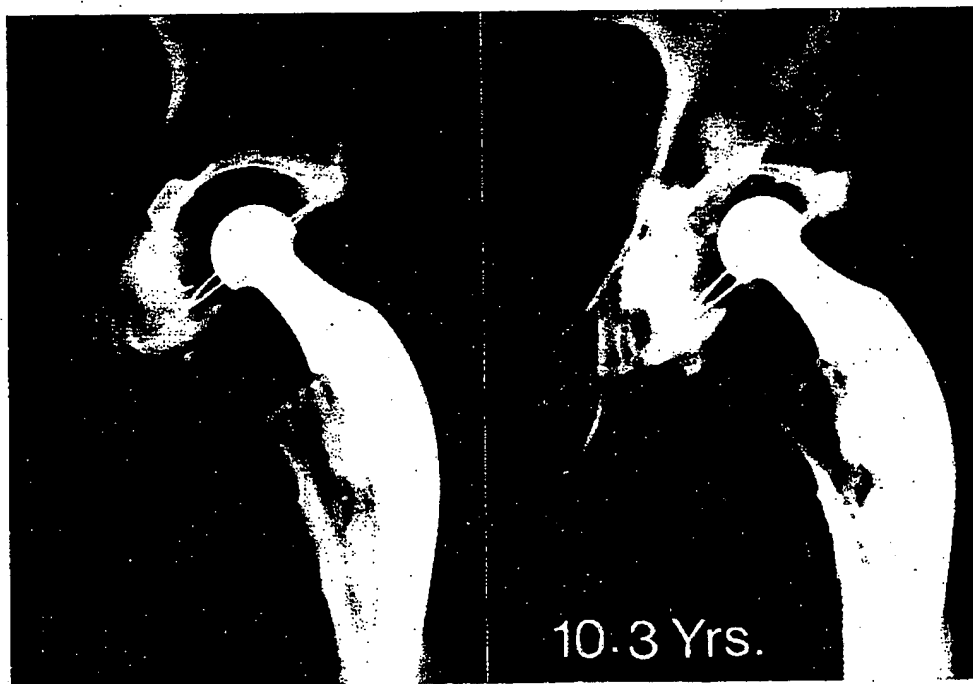


FIG. 8

Anteroposterior radiographs made immediately after insertion of a twenty-two-millimeter prosthesis and 10.3 years later, showing lysis of the proximal part of the femur with four millimeters of acetabular wear.

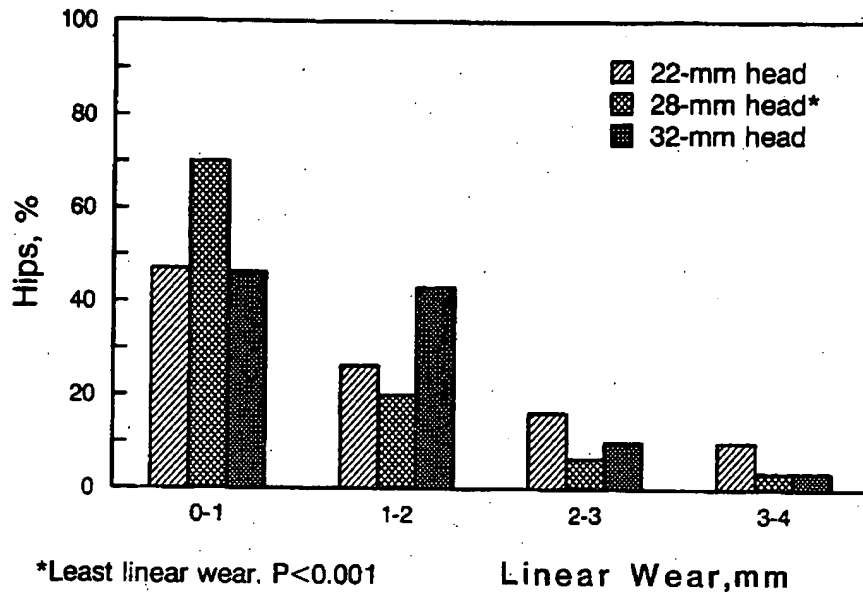


FIG. 9

Linear wear as a function of femoral head size.

Of the thirty-two-millimeter heads (Aufranc-Turner or Müller), 10 per cent had more than two millimeters of linear wear; 2 per cent, more than three millimeters; and none, more than four millimeters. The mean linear wear was 1.10 ± 0.7 millimeters (range, zero to 3.5 millimeters). The mean rate of linear wear was 0.10 ± 0.06 millimeter per year (range, 0 to 0.32 millimeter). Estimates of volumetric wear revealed that 49 per cent of the components had less than 800 cubic millimeters of wear and 52 per cent had more than that. The mean volumetric wear was 911 ± 547 cubic millimeters (range, thirty to 2,811 cubic millimeters).

The mean rate of volumetric wear was 84.1 ± 49.8 cubic millimeters per year (range, three to 256 cubic millimeters per year).

Both linear wear and rate of linear wear were significantly less in the twenty-eight-millimeter group than in the other two groups ($p < 0.001$, analysis of variance). The thirty-two-millimeter group had a significantly greater average volume and rate of volumetric wear than either the twenty-two-millimeter or the twenty-eight-millimeter group ($p < 0.001$, analysis of variance) (Figs. 9, 10, and 11).

The general direction of maximum linear wear was

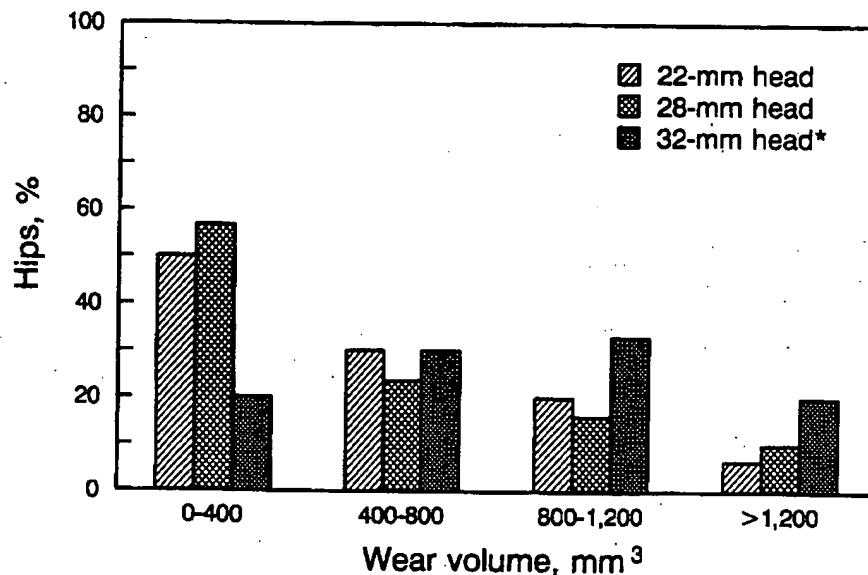


FIG. 10

Volume of debris from wear as a function of femoral head size.

cephalad and medial in all three groups, but this wear averaged significantly less in the twenty-eight-millimeter group ($\alpha = -2 \pm 17$ degrees) than in either the twenty-two-millimeter group ($\alpha = -22 \pm 16$ degrees) or the thirty-two-millimeter group ($\alpha = -15 \pm 16$ degrees). There was a slightly but significantly higher average initial thickness of the polyethylene at the point of maximum wear in the twenty-two-millimeter group (10.3 ± 1.1 millimeters) than in the twenty-eight-millimeter group (9.7 ± 1.8 millimeters) or the thirty-two-millimeter group (9.6 ± 1.9 millimeters).

The association of greater body weight with increasing volumetric wear was significant ($r = 0.10$, $p < 0.05$, Spearman rank-correlation coefficient). Linear wear was not significantly associated with body weight ($r = 0.07$, $p = 0.15$, Spearman rank-correlation coefficient).

The median width of the radiolucent line in acetabular Zone 1²¹ in the thirty-two-millimeter group was 2.4 millimeters, and the mean was 2.1 millimeters (range, zero to sixteen millimeters). In the twenty-two-millimeter group, the median width was 1.0 millimeter and the mean, 1.4 millimeter (range, zero to 7.0 millimeters). In the twenty-eight-millimeter group, the median width was 0.9 millimeter and the mean, 1.1 millimeters (range, zero to 5.0 millimeters). The width of the radiolucent line that was associated with the thirty-two-millimeter components was statistically greater than that associated with the smaller components ($p < 0.05$, Kruskal-Wallis test).

Linear and volumetric wear were both associated with increased resorption of the proximal part of the femoral neck ($p < 0.01$) and with increased lysis of the proximal part of the femur ($p < 0.01$). There was no statistically significant

TABLE II
CORRELATION OF LINEAR AND VOLUMETRIC WEAR
WITH BODY WEIGHT AND RADIOGRAPHIC PARAMETERS

	Linear Wear		Volumetric Wear	
	Correlation Coefficient	P Value	Correlation Coefficient	P Value
Body weight	0.07	>0.05	0.10	<0.05
Resorption of prox. part of femoral head	0.22	<0.001	0.23	<0.001
Femoral osteolysis	0.15	<0.005	0.11	<0.04
Radiolucent line at femoral bone-cement interface				
Zone 1	0.05	>0.05	0.08	>0.05
Zone 7	0.06	>0.05	0.05	>0.05

association of linear or volumetric wear with a radiolucent line at the bone-cement interface in femoral Zone 1 or 7³⁵.

The reliability of the radiographic measurements is shown in Table II. A mean discrepancy of only 0.075 millimeter (range, zero to 0.4 millimeter) was found between the radiographic and the direct measurements of acetabular thickness. These data indicate that the radiographic technique was reliable.

Discussion

Clarke and Amstutz¹⁶ and Clarke et al.^{17,18} sharply and justifiably criticized previous methods of radiographic measurement of wear of the acetabular polyethylene. Concerns about both the initial technique, described by Charnley and Cupic¹², which used a single radiograph, and that described by Charnley and Halley¹³ are based on the question of ac-

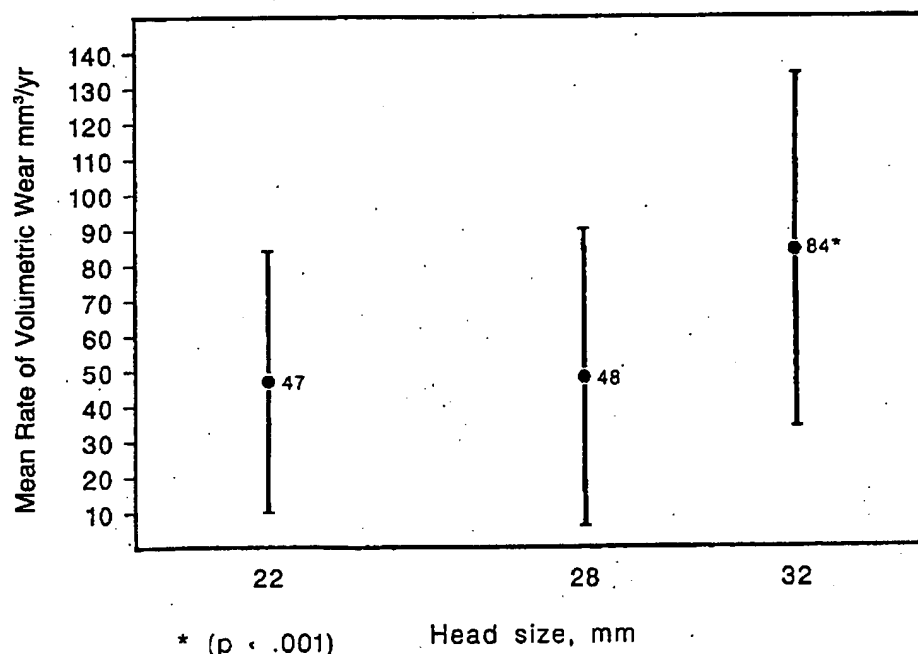


FIG. 11

Rate of volumetric wear (mean and standard deviation), by head size of the femoral component, over a ten-year period.

curacy of the measurements to the implanted position of the wire marker. Griffith et al.³³ defended those radiographic techniques but noted that the wire marker must be within 10 degrees of the coronal plane. Wroblewski⁸¹ showed a remarkably good correlation between radiographic and direct measurements of casts of retrieved polyethylene cups. In the present study, use of the cement-prosthesis interface rather than wire markers as a proximal landmark for measurement entirely eliminated the concern about the effect of the orientation of the wire marker. The cement-prosthesis interface is the most proximal extent of the polyethylene in the coronal plane and is a readily identifiable landmark. Hence, it provides an accurate landmark for measurement of wear, if one assumes that most wear takes place in the coronal plane and that the pelvis was in the same position in relation to the x-ray beam and the cassette for both sets of radiographs. Because of this consideration, we used non-portable equipment, with a technique that was standardized for our institution.

The data from sectioned cups and the corresponding radiographs indicated that there was a good correlation between the radiographic determination of thickness of the acetabular polyethylene and the determination by direct measurement. We believe that the technique described in this report is more accurate and consistent than previously described methods and that it may be used to study the relationship of the amount of wear of the acetabular cup to the size of the prosthetic femoral head.

As far as we can tell, this report is the first long-term clinical study from a single institution in which standardized radiographs were used to compare wear of the polyethylene as a function of size of the prosthetic head in similar populations of patients. Furthermore, the report of the statistically significant positive correlation between body weight and volumetric wear ($p < 0.03$) is the first, to our knowledge.

Because of the number of uncontrolled variables, despite the advantages of this technique of measurement, conclusions about the absolute amounts of wear of acetabular cups do not seem justified at this point. However, our study does provide reliable information on the relative wear of the three sizes of femoral head.

The data that are reported here compare favorably with those in previous clinical radiographic evaluations. Reports of mean rates of wear in Charnley low-friction arthroplasty (with the twenty-two-millimeter head) have ranged from 0.07 to 0.21 millimeter per year, with most rates ranging from 0.10 to 0.15 millimeter per year^{12,13,19,36,82}. The mean rate for all of these studies is 0.10 millimeter per year, and the mean rate for the present study is 0.12 millimeter per year. The only other study of the rate of wear of the thirty-two-millimeter head of which we are aware reported an average of 0.2 millimeter per year⁶⁴, which is more than the 0.1 millimeter per year reported here. We are aware of no other clinical data on the rate of wear of twenty-eight-millimeter heads in total hip arthroplasties.

Charnley et al.¹⁴ determined the size of the prosthetic

femoral head that had the slowest penetration of the acetabular cup and the least volume of debris from wear. Galante and Rostoker³⁰ used data on basic wear for theoretical calculations of ideal head size to minimize volume of debris for both standard and carbon-fiber-reinforced polyethylene. Both studies concluded that the twenty-two-millimeter head is better than the thirty-two-millimeter head when it articulates with standard high-density polyethylene.

Our data show a significantly lower rate of linear wear for the prosthesis with the twenty-eight-millimeter head. The volume of debris from wear and the rate of volumetric wear for the thirty-two-millimeter head were significantly greater than those for the twenty-two-millimeter and twenty-eight-millimeter heads. These results suggest that the best characteristics of wear of metal-polyethylene total hip designs are realized with a femoral head size in the middle range of current clinical use.

The biological response to wear of the polyethylene may have profound effects on local tissue and on fixation of the implant^{2,5,7-9,20,21,37,39-41,46,47,50-52,67,71,76-78}. Most long-term follow-up studies of total hip replacement with polyethylene acetabular components have reported essentially no mechanical failures on the basis of wear of the polyethylene^{4,12,19,31,33,36,62,63,68}. Charnley and Cupic^{12,19} discussed the potential effect of debris from wear locally; they noted no significant relationship between wear of the socket and resorption of the proximal part of the femoral neck. Numerous factors were found to influence the radiographic appearance of the bone-cement interface³⁵.

It was not our intention to focus on the adverse effect of debris from wear on the bone-cement interface. Yet, because one major concern about wear is related to its possible influence on this interface⁸², it was appropriate to record the radiographic appearance of the proximal part of the femur. The positive correlation of volume of debris from wear and of linear wear with resorption of the proximal part of the femoral neck and osteolysis of the proximal part of the femur is thus worth noting. These findings may prove important as more data are gathered.

In the past, the choice of femoral head size has been based on theoretical evaluations of articular stability and frictional torque^{53,66,75}. Larger head sizes are theoretically associated with greater stability of the joint but also with greater frictional torque at the acetabular bone-cement interface. In a previous study from our institution, no statistically significant difference in the rate of dislocation as a function of the size of the femoral head was determined⁷⁹. More recently, the rate of revision for acetabular loosening was shown to be greater for cemented cups that were not backed with metal and were used with thirty-two-millimeter prosthetic heads than for those used with twenty-two and twenty-eight-millimeter heads⁴⁸.

On the basis of the experience in our institution with stability, acetabular loosening, and wear, the use of a prosthetic femoral head of intermediate size, such as a twenty-eight-millimeter head, appears to provide the best wear characteristics in total hip arthroplasty.

References

1. ATKINSON, J. R.; DOWLING, J. M.; and CICEK, R. Z.: Materials for Internal Prostheses: The Present Position and Possible Future Developments. *Biomaterials*, 1: 89-96, 1980.
2. AUSTIN, R. T., and STONEY, P. J.: Granulomatosis of Bone from High Density Polyethylene. *Injury*, 13: 414-418, 1982.
3. BARTEL, D. L.; BICKNELL, V. L.; and WRIGHT, T. M.: The Effect of Conformity, Thickness, and Material on Stresses in Ultra-High Molecular Weight Components for Total Joint Replacement. *J. Bone and Joint Surg.*, 68-A: 1041-1051, Sept. 1986.
4. BECKENBAUGH, R. D., and ILSTRUP, D. M.: Total Hip Arthroplasty. A Review of Three Hundred and Thirty-three Cases with Long Follow-up. *J. Bone and Joint Surg.*, 60-A: 306-313, April 1978.
5. BELL, R. S.; HA'ERI, G. B.; GOODMAN, S. B.; and FORNASIER, V. L.: Case Report 246. *Skel. Radiol.*, 10: 201-204, 1983.
6. BEUTLER, H.; LEHMANN, M.; and STAHL, G.: Wear Behavior of Medical Engineering Materials. *Wear*, 33: 337-350, 1975.
7. BLACK, JONATHAN: The Future of Polyethylene (editorial). *J. Bone and Joint Surg.*, 60-B(3): 303-306, 1978.
8. BROWN, I. W., and RING, P. A.: Osteolytic Changes in the Upper Femoral Shaft following Porous-Coated Hip Replacement. *J. Bone and Joint Surg.*, 67-B(2): 218-221, 1985.
9. BULLOUGH, P. G.: Tissue Reaction to Wear Debris Generated from Total Hip Replacements. *In The Hip: Proceedings of the First Open Meeting of The Hip Society*, pp. 80-91. St. Louis, C. V. Mosby, 1973.
10. CHAO, E. Y. S.; AXMEAR, F. E.; and COVENTRY, M. B.: A Quantitative Method for the Determination of the Polyethylene Cup Wear in Total Hip Arthroplasty. *Proc. Ann. Conf. Eng. Med. and Biol.*, 15: 152, 1973.
11. CHARNLEY, JOHN: Low Friction Principle. *In Low Friction Arthroplasty of the Hip. Theory and Practice*, pp. 3-15. New York, Springer, 1979.
12. CHARNLEY, JOHN, and CUPIC, ZORAN: The Nine and Ten Year Results of the Low-Friction Arthroplasty of the Hip. *Clin. Orthop.*, 95: 9-25, 1973.
13. CHARNLEY, JOHN, and HALLEY, D. K.: Rate of Wear in Total Hip Replacement. *Clin. Orthop.*, 112: 170-179, 1975.
14. CHARNLEY, J.; KAMANGAR, A.; and LONGFIELD, M. D.: The Optimum Size of Prosthetic Heads in Relation to the Wear of Plastic Sockets in Total Replacement of the Hip. *Med. and Biol. Eng.*, 7: 31-39, 1969.
15. CLARKE, I. C.: Wear of Polymeric Prosthesis — Clinical Reality, Retrieved Implants, and Laboratory Predictions. *In Implant Retrieval: Material and Biological Analysis*, pp. 471-499. Special Publication 601. Washington, D.C., National Bureau of Standards, 1980.
16. CLARKE, I. C., and AMSTUTZ, H. C.: Validity of X-Ray Wear-Measurements. *Trans. Orthop. Res. Soc.*, 1: 80, 1976.
17. CLARKE, I. C.; BLACK, K.; RENNIE, C.; and AMSTUTZ, H. C.: Can Wear in Total Hip Arthroplasties Be Assessed from Radiographs? *Clin. Orthop.*, 121: 126-142, 1976.
18. CLARKE, I. C.; KIRKPATRICK, J. S.; MILLER, B. D.; and AMSTUTZ, H. C.: Troubleshooting Muller Radiographic Wear Measurements. *Trans. Orthop. Res. Soc.*, 4: 70, 1979.
19. CUPIC, ZORAN: Long-Term Follow-up of Charnley Arthroplasty of the Hip. *Clin. Orthop.*, 141: 28-43, 1979.
20. DANNENMAIER, W. C.; HAYNES, D. W.; and NELSON, C. L.: Granulomatous Reaction and Cystic Bony Destruction Associated with High Wear Rate in a Total Knee Prosthesis. *Clin. Orthop.*, 198: 224-230, 1985.
21. DELEE, J. G., and CHARNLEY, JOHN: Radiological Demarcation of Cemented Sockets in Total Hip Replacement. *Clin. Orthop.*, 121: 20-32, 1976.
22. DOWLING, J. M.: Wear Analysis of Retrieved Prostheses. *In Biocompatible Polymers, Metals, and Composites*, pp. 407-425. Edited by Michael Szycher. Lancaster, Pennsylvania, Technomic, 1983.
23. DOWLING, J. M.; ATKINSON, J. R.; DOWSON, D.; and CHARNLEY, JOHN: The Characteristics of Acetabular Cups Worn in the Human Body. *J. Bone and Joint Surg.*, 60-B(3): 375-382, 1978.
24. DOWSON, D.; ATKINSON, J. R.; and BROWN, K.: The Wear of High Molecular Weight Polyethylene with Particular Reference to Its Use in Artificial Human Joints. *Polymer Sci. and Technol.*, 5: 533-551, 1974.
25. DUMBLETON, J. H.: Prosthesis Materials and Devices: A Review. *In Biocompatible Polymers, Metals, and Composites*, pp. 427-460. Edited by Michael Szycher. Lancaster, Pennsylvania, Technomic, 1983.
26. DUMBLETON, J. H., and SHEN, C.: Wear Behavior of Ultrahigh Molecular-Weight Polyethylene. *Wear*, 37: 279-289, 1976.
27. DUMBLETON, J. H.; SHEN, C.; and MILLER, E. H.: Study of the Wear of Some Materials in Connection with Total Hip Replacement. *Wear*, 29: 163-171, 1974.
28. ESCALAS, FELIX; GALANTE, JORGE; ROSTOKER, WILLIAM; and COOGAN, PHILIP: Biocompatibility of Materials for Total Joint Replacement. *J. Biomed. Mater. Res.*, 10: 175-195, 1976.
29. EYERER, P.: Biodegradation of UHMW Polyethylene in Joint Endoprosthesis. *In Proceedings of the Second World Congress on Biomaterials, Tenth Annual Meeting of the Society for Biomaterials*, Washington, D.C., p. 68, 1984.
30. GALANTE, J. O., and ROSTOKER, WILLIAM: Wear in Total Hip Prostheses. An Experimental Evaluation of Candidate Materials. *Acta Orthop. Scandinavica, Supplementum* 145, 1973.
31. GAUSSENS, G.; BERTHET, J.; CORNET, L.; and NICAISE, M.: Improvement of Creep and Wear Properties of Polyethylenes. *In Proceedings of The Second World Congress on Biomaterials, Tenth Annual Meeting of the Society for Biomaterials*, Washington, D.C., p. 314, 1984.
32. GOLD, B. L., and WALKER, P. S.: Variables Affecting the Friction and Wear of Metal-on-Plastic Total Hip Joints. *Clin. Orthop.*, 100: 270-278, 1974.
33. GRIFFITH, M. J.; SEIDENSTEIN, M. K.; WILLIAMS, D.; and CHARNLEY, J.: Socket Wear in Charnley Low Friction Arthroplasty of the Hip. *Clin. Orthop.*, 137: 37-47, 1978.
34. GROBBELAAR, C. J.; DU PLESSIS, T. A.; and MARAIS, F.: The Radiation Improvement of Polyethylene Prostheses. A Preliminary Study. *J. Bone and Joint Surg.*, 60-B(3): 370-374, 1978.
35. GRUEN, T. A.; MCNEICE, G. M.; and AMSTUTZ, H. C.: "Modes of Failure" of Cemented Stem-Type Femoral Components. A Radiographic Analysis of Loosening. *Clin. Orthop.*, 141: 17-27, 1979.
36. HALLEY, D. K., and WROBLEWSKI, B. M.: Long-Term Results of Low-Friction Arthroplasty in Patients 30 Years of Age or Younger. *Clin. Orthop.*, 211: 43-50, 1986.
37. HEILMANN, K.; DIEZEL, P. B.; ROSSNER, J. A.; and BRINKMANN, K. A.: Morphological Studies in Tissues Surrounding Alloarthroplastic Joints. *Virchows Arch.*, 366: 93-106, 1975.
38. HOMERIN, M.; CHRISTEL, P.; DRYLL, A.; and GAUSSENS, G.: In-Vivo Evaluation of Tissue Tolerance of PTFE-Grafted Polyethylene Particles. *In Proceedings of the Second World Congress on Biomaterials, Tenth Annual Meeting of the Society for Biomaterials*, Washington, D.C., p. 67, 1984.
39. JASTY, M. J.; FLOYD, W. E., III; SCHILLER, A. L.; GOLDRING, S. R.; and HARRIS, W. H.: Localized Osteolysis in Stable, Non-Septic Total Hip Replacement. *J. Bone and Joint Surg.*, 68-A: 912-919, July 1986.
40. KIM, W. C.; NOTTINGHAM, P.; LUBEN, R.; AMSTUTZ, H. C.; MIRRA, J. M.; and FINERMAN, G. A. M.: Mechanism of Osteolysis in Aseptic Loose Total Hip Replacements. *Trans. Orthop. Res. Soc.*, 13: 500, 1988.
41. LERAY, J. L., and CHRISTEL, P.: Tissue Tolerance of Wear Debris from Arthroplasties. *In Advances in Biomaterials*, pp. 197-206. Edited by G. D. Winter, D. F. Gibbons, and H. Plenk, Jr. New York, Wiley, 1982.
42. MCKELLOP, H. A.; CLARKE, I. C.; MARKOLF, K. L.; and AMSTUTZ, H. C.: The Importance of Fluid Absorption, Creep and Lubricant in Wear Measurements of Polymers for Prosthetic Bearings. *Trans. Orthop. Res. Soc.*, 1: 82, 1976.
43. MCKELLOP, H.; CLARKE, I.; MARKOLF, K.; and AMSTUTZ, H.: Friction and Wear Properties of Polymer, Metal, and Ceramic Prosthetic Joint Materials Evaluated on a Multichannel Screening Device. *J. Biomed. Mater. Res.*, 15: 619-653, 1981.
44. MCKELLOP, H.; GRIFFIN, G.; CLARKE, I.; and MARKOLF, K.: Increased Wear of UHMW Polyethylene after Gamma Radiation Sterilization. *Trans. Orthop. Res. Soc.*, 5: 99, 1980.
45. MCKELLOP, H.; HOSSEINI, A.; BURGOYNE, K.; and CLARKE, I.: Polyethylene Wear against Titanium Alloy Compared to Stainless Steel and Cobalt-Chromium Alloys. *In Proceedings of the Second World Congress on Biomaterials, Tenth Annual Meeting of the Society for Biomaterials*, Washington, D.C., p. 313, 1984.
46. MIRRA, J. M.; MARDER, R. A.; and AMSTUTZ, H. C.: The Pathology of Failed Total Joint Arthroplasty. *Clin. Orthop.*, 170: 175-183, 1982.

47. MIRRA, J. M.; AMSTUTZ, H. C.; MATOS, MAXIMO; and GOLD, RICHARD: The Pathology of the Joint Tissues and Its Clinical Relevance in Prosthesis Failure. *Clin. Orthop.*, 117: 221-240, 1976.
48. MORREY, B. F., and ILSTRUP, DUANE: Size of the Femoral Head and Acetabular Revision in Total Hip-Replacement Arthroplasty. *J. Bone and Joint Surg.*, 71-A: 50-55, Jan. 1989.
49. NEWMAN, P. H., and SCALES, J. T.: The Unsuitability of Polythene for Movable Weight-Bearing Prostheses. Report of a Case of Cup Arthroplasty of the Hip. *J. Bone and Joint Surg.*, 33-B(3): 392-398, 1951.
50. PAZZAGLIA, Ugo, and BYERS, P. D.: Fractured Femoral Shaft through an Osteolytic Lesion Resulting from the Reaction to a Prosthesis. A Case Report. *J. Bone and Joint Surg.*, 66-B(3): 337-339, 1984.
51. PIZZOFERRATO, A.: Evaluation of the Tissue Response to the Wear Products of the Hip Joint Endo-Arthroprosthesis. *Biomater. Med. Devices and Artif. Organs*, 7: 257-262, 1979.
52. REVELL, P. A.; WEIGHTMAN, B.; FREEMAN, M. A. R.; and ROBERTS, B. V.: The Production and Biology of Polyethylene Wear Debris. *Arch. Orthop. and Traumat. Surg.*, 91: 167-181, 1978.
53. RITTER, M. A.; STRINGER, E. A.; LITTELL, D. A.; and WILLIAMS, J. G.: Correlation of Prosthetic Femoral Head Size and/or Design with Longevity of Total Hip Arthroplasty. *Clin. Orthop.*, 176: 252-257, 1983.
54. ROSE, R. M., and RADIN, E. L.: Wear of Polyethylene in the Total Hip Prosthesis. *Clin. Orthop.*, 170: 107-115, 1982.
55. ROSE, R. M.; CIMINO, W. R.; ELLIS, E.; and CRUGNOLA, A. N.: Exploratory Investigations on the Structure Dependence of the Wear-Resistance of Polyethylene. *Wear*, 77: 89-104, 1982.
56. ROSE, R. M.; CRUGNOLA, A. N.; CIMINO, W. R.; and RIES, M. D.: The In-Vivo Performance of Polyethylene Components of Total Joint Replacements. In *Implant Retrieval: Material and Biological Analysis*, pp. 3-28. Special Publication 601. Washington, D.C., National Bureau of Standards, 1980.
57. ROSE, R. M.; GOLDFARB, H. V.; ELLIS, E.; and CRUGNOLA, A. M.: On the Pressure-Dependence of the Wear of Ultrahigh Molecular-Weight Polyethylene. *Wear*, 92: 99-111, 1983.
58. ROSE, R. M.; CRUGNOLA, A.; RIES, M.; CIMINO, W. R.; PAUL, I.; and RADIN, E. L.: On the Origins of High *in Vivo* Wear Rates in Polyethylene Components of Total Joint Prostheses. *Clin. Orthop.*, 145: 277-286, 1979.
59. ROSE, R. M.; SCHNEIDER, H.; RIES, M.; PAUL, I.; CRUGNOLA, A.; SIMON, S. R.; and RADIN, E. L.: Quantitative Recovery of Polyethylene Wear Debris and the Relative Wear Rates of Total Joint Prostheses. *Trans. Orthop. Res. Soc.*, 4: 68, 1979.
60. ROSE, R. M.; NUSBAUM, H. J.; SCHNEIDER, H.; RIES, M.; PAUL, I.; CRUGNOLA, A.; SIMON, S. R.; and RADIN, E. L.: On the True Wear Rate of Ultra High-Molecular-Weight Polyethylene in the Total Hip Prosthesis. *J. Bone and Joint Surg.*, 62-A: 537-549, June 1980.
61. ROSTOKER, W.; CHAO, E. Y. S.; and GALANTE, J. O.: The Appearances of Wear on Polyethylene — A Comparison of *in Vivo* and *in Vitro* Wear Surfaces. *J. Biomed. Mater. Res.*, 12: 317-335, 1978.
62. SALVATI, E. A.; WRIGHT, T. M.; BURSTEIN, A. H.; and JACOBS, B.: Fracture of Polyethylene Acetabular Cups. Report of Two Cases. *J. Bone and Joint Surg.*, 61-A: 1239-1242, Dec. 1979.
63. SALVATI, E. A.; WILSON, P. D., JR.; JOLLEY, M. N.; VAKILI, FAYEGH; AGLIETTI, PAOLO; and BROWN, G. C.: A Ten-Year Follow-up Study of Our First One Hundred Consecutive Charnley Total Hip Replacements. *J. Bone and Joint Surg.*, 63-A: 753-767, June 1981.
64. SCHEIER, H., and SANDEL, J.: Wear Affecting the Plastic Cup in Metal-Plastic Endoprostheses. In *Total Hip Prosthesis*, pp. 186-190. Edited by N. Gschwend and H. U. Debrunner. Baltimore, Williams and Wilkins, 1976.
65. SCLIPPA, ERMES, and PIEKARSKI, K.: Carbon Fiber Reinforced Polyethylene for Possible Orthopedic Uses. *J. Biomed. Mater. Res.*, 7: 59-70, Jan. 1973.
66. SEMLITSCH, M.: Technical Progress in Artificial Hip Joints. In *Total Hip Prosthesis*, pp. 256-278. Edited by N. Gschwend and H. U. Debrunner. Baltimore, Williams and Wilkins, 1976.
67. SPECTOR, M.; REESE, N.; and HEWAN-LOWE, K.: Response to Particulate Polysulfane and Polyethylene in an Animal Model for Tumorigenicity Testing. In *Proceedings of the Second World Congress on Biomaterials, Tenth Annual Meeting of the Society for Biomaterials, Washington, D.C.*, p. 273, 1984.
68. STAUFFER, R. N.: Ten-Year Follow-up Study of Total Hip Replacement. With Particular Reference to Roentgenographic Loosening of the Components. *J. Bone and Joint Surg.*, 64-A: 983-990, Sept. 1982.
69. STERN, L. S.; MANLEY, M. T.; and PARR, J.: Particle Size Distribution of Wear Debris from Polyethylene and Carbon Reinforced Acetabular Components. In *Proceedings of the Second World Congress on Biomaterials, Tenth Annual Meeting of the Society for Biomaterials, Washington, D.C.*, p. 66, 1984.
70. SWANSON, S. A. V., and FREEMAN, M. A. R.: Friction, Lubrication and Wear. In *The Scientific Basis of Joint Replacement*, pp. 46-85. New York, Wiley, 1977.
71. SWANSON, S. A. V., and FREEMAN, M. A. R.: The Tissue Response to Total Joint Replacement Prostheses. In *The Scientific Basis of Joint Replacement*, pp. 86-129. New York, Wiley, 1977.
72. TETIK, R. D.; GALANTE, J. O.; and ROSTOKER, WILLIAM: A Wear Resistant Material for Total Joint Replacement — Tissue Biocompatibility of an Ultra-High Molecular Weight (UHMW) Polyethylene-Graphite Composite. *J. Biomed. Mater. Res.*, 8: 231-250, Sept. 1974.
73. WALKER, P. S.: The Reduction of Wear in Artificial Joints. *Trans. Orthop. Res. Soc.*, 1: 81, 1976.
74. WALKER, P. S., and BULLOUGH, P. G.: The Effects of Friction and Wear in Artificial Joints. *Orthop. Clin. North America*, 4: 275-293, 1973.
75. WEIGHTMAN, B. O.; PAUL, I. L.; ROSE, R. M.; SIMON, S. R.; and RADIN, E. L.: A Comparative Study of Total Hip Replacement Prostheses. *J. Biomech.*, 6: 299-311, 1973.
76. WILLERT, H. G., and SEMLITSCH, M.: Tissue Reactions to Plastic and Metallic Wear Products of Joint Endoprostheses. In *Total Hip Prosthesis*, pp. 205-239. Edited by N. Gschwend and H. U. Debrunner. Baltimore, Williams and Wilkins, 1976.
77. WILLERT, H.-G., and SEMLITSCH, M.: Reactions of the Articular Capsule to Wear Products of Artificial Joint Prostheses. *J. Biomed. Mater. Res.*, 11: 157-164, March 1977.
78. WILLERT, H. G.; BUCHHORN, G.; BUCHHORN, V.; and SEMLITSCH, M.: Tissue Response to Wear Debris in Artificial Joints. In *Implant Retrieval: Material and Biological Analysis*, pp. 239-267. Special Publication 601. Washington, D.C., National Bureau of Standards, 1980.
79. WOO, R. Y. G., and MORREY, B. F.: Dislocations after Total Hip Arthroplasty. *J. Bone and Joint Surg.*, 64-A: 1295-1306, Dec. 1982.
80. WROBLEWSKI, B. M.: Wear of High-Density Polyethylene on Bone and Cartilage. *J. Bone and Joint Surg.*, 61-B(4): 498-500, 1979.
81. WROBLEWSKI, B. M.: Direction and Rate of Socket Wear in Charnley Low-Friction Arthroplasty. *J. Bone and Joint Surg.*, 67-B(5): 757-761, 1985.
82. WROBLEWSKI, B. M.: 15-21-Year Results of the Charnley Low-Friction Arthroplasty. *Clin. Orthop.*, 211: 30-35, 1986.

The role of acetabular component screw holes and/or screws in the development of pelvic osteolysis

T P Schmalzried^{1,2*}, I C Brown^{1,2}, H C Amstutz², C A Engh³ and W H Harris⁴

¹ Harbor-UCLA Medical Center, Torrance, California, USA

² Joint Replacement Institute, Los Angeles, California, USA

³ Anderson Orthopaedic Research Institute, Arlington, Virginia, USA

⁴ Orthopaedic Biomechanics Laboratory, Massachusetts General Hospital, Boston, Massachusetts, USA

Abstract: Anecdotal reporting of osteolysis around cementless modular acetabular components with holes through the metal shell and/or iliac fixation screws has raised concern that such designs may generate excessive particulate debris and/or permit direct access of particulate debris to iliac bone. To address this issue, incidence data are reported on 513 total hip replacements from six different single-surgeon series of total hip arthroplasties performed with six different porous ingrowth acetabular components. With follow-up ranging from 40 to 108 months, a total of 45 pelvic osteolytic lesions were observed (8.8 per cent).

Pelvic osteolysis was seen nearly as frequently in the ischium and pubis (21 lesions) as it was in the ilium (24 lesions). It was not possible to explain ischial and pubic osteolysis by holes and/or screws through the acetabular component shell. There was no direct correlation between the presence of screw holes or screws and the incidence of pelvic osteolysis. The incidence of pelvic osteolysis around modular components with holes through the shell was 4.5 per cent (14 of 313 hips). The incidence of pelvic osteolysis with solid-shell components was 15.5 per cent (31 of 200). The incidence of pelvic osteolysis around acetabular reconstructions with screws was 2.3 per cent (3 of 133). The incidence of pelvic osteolysis in reconstructions without screws was 11.1 per cent (32 of 380). The incidence of pelvic osteolysis in one-piece acetabular components (polyethylene pre-fixed in the metal shell) was 12.7 per cent (21 of 165) and the incidence of pelvic osteolysis with the modular components was 6.9 per cent (24 of 348). In each comparison, the incidence of pelvic osteolysis was actually *lower* in the group assumed to be at increased risk.

Based on this review there does not appear to be a direct relationship between holes and/or screws through an acetabular component and the development of pelvic osteolysis. The incidence of pelvic osteolysis was associated with larger head diameters and longer follow-up. While screw holes may provide an access channel in specific cases, the present data indicate that the simple elimination of holes through the acetabular shell will not eliminate pelvic osteolysis.

Regardless of other acetabular component design features, joint fluid and polyethylene wear particles from the femoral-acetabular articulation can gain access to bone behind an acetabular component via the peripheral implant-bone interface through regions without sufficient contact or tissue ingrowth. The development of pelvic osteolysis is multifactorial and includes the total volumetric wear of polyethylene as well as *specific* features of the acetabular component design and reconstruction technique.

Keywords: hip replacement, acetabulum, wear, osteolysis

1 INTRODUCTION

Reporting of osteolysis around cementless modular acetabular components with holes through the metal shell and/or iliac fixation screws has raised concern that such

designs may generate excessive particulate debris and/or permit direct access of particulate debris to iliac bone [1-3] (Fig. 1). However, incidence data have not been reported for these scattered cases. If holes and/or screws through the acetabular component shell predispose to pelvic osteolysis, then an increased incidence of pelvic osteolysis would be expected with these reconstructions.

To address this issue, incidence data on pelvic osteolysis in 513 total hip replacements are presented from six

The MS was received on 20 December 1995 and was accepted after revision for publication on 19 November 1997.

* Corresponding author: Joint Replacement Institute, 2400 South Flower Street, Los Angeles, CA 90007, USA.

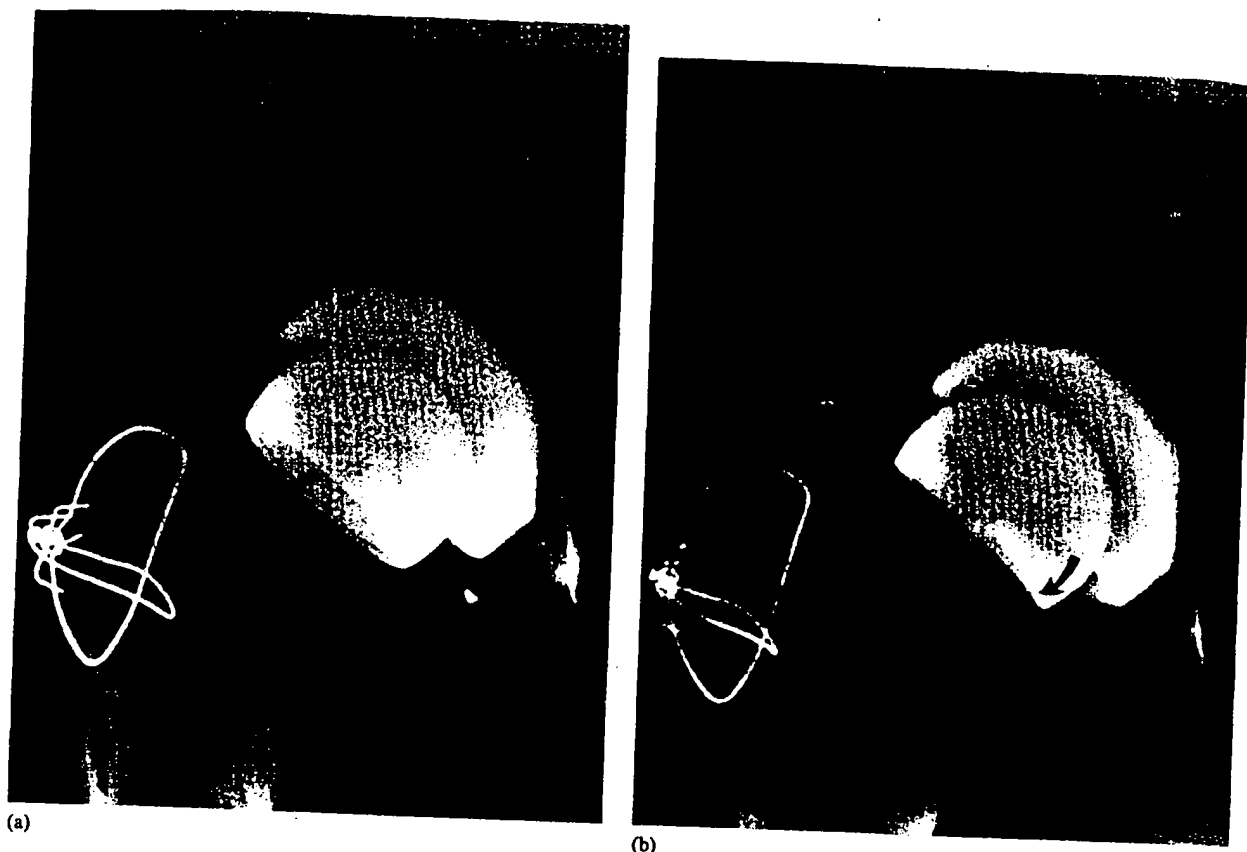


Fig. 1 (a) Antero-posterior radiograph of a right hip taken postoperatively following a porous surface replacement (PSR) arthroplasty (Series 5). The large diameter of these components results in a volumetric wear of polyethylene that is 4–10 times higher than that produced by a conventional 28 mm diameter bearing for an equivalent number of cycles. (b) Antero-posterior radiograph of the same right hip taken approximately 5 years later. Note the cystic, expansile or balloon-like form of bone resorption (osteolysis) occurring in the ilium (arrows). The radiograph suggests that there is a defect in the implant–bone interface at the supero-lateral margin of the acetabulum leading to the osteolytic lesion. This communication between the traditional joint space and the ilium was confirmed at reoperation

different single-surgeon series of total hip arthroplasties performed with different porous ingrowth acetabular reconstructions. The acetabular components used in these series have different design features which include one-piece versus modular construction, solid shells versus shells with holes and fixation screws versus no screws. There was standardization of the radiographic observations because the same observer (T.P.S.) participated in all six radiographic reviews. Clinical and radiographic results of several of these series have been published [4–8]. The factors contributing to pelvic osteolysis have become such an important and controversial issue that these specific data are presented as a distinct report.

2 MATERIALS AND METHODS

The same investigator (T.P.S.) has participated in the radiographic review of six separate single-surgeon series of

total hip arthroplasties performed with porous ingrowth acetabular components. Series 1 (surgeries performed by W.H.H.) consisted of 50 hips reconstructed with a solid, one-piece (non-modular), beaded, cobalt–chrome acetabular component stabilized by three screws placed through three peripheral flanges which protruded from the rim of the component (Acetabular Reconstruction Component, or ARC, Howmedica, Rutherford, New Jersey). The component has similar porous coating technology as the original PCA (Porous Coated Anatomic, Howmedica). Hemispherical reamers were used to prepare the acetabulum such that the outer diameter of the porous acetabular component was equal to the outer diameter of the last reamer used. All of the femoral components were non-modular and cemented (HD-2, Howmedica). Forty-eight of the femoral heads were 26 mm in diameter and two were 22 mm. The average patient age was 61 years (ranging from 23 to 83). Follow-up ranged from 5 to 8 years with an average of 85 months [7].

Series 2 (surgeries performed by W.H.H.) consisted of 83 hips with a titanium fibre-mesh acetabular component with a modular polyethylene liner and multiple screw holes through the shell stabilized by two to five screws (average of three) (Harris-Galante Porous, or HGP, Zimmer, Warsaw, Indiana). Hemispherical reamers were used to prepare the acetabulum such that the outer diameter of the porous acetabular component was equal to the outer diameter of the last reamer used. All femoral components had modular heads. Forty of the components (Precoat, Zimmer) were cemented and 43 were cementless (Harris-Galante Porous, Zimmer). The great majority of these heads were 26 mm and the largest head diameter was 28 mm. The average patient age was 59 years (ranging from 23 to 79). Follow-up ranged from 5 to 7 years with an average of 68 months [6].

Series 3 (surgeries performed by Dr Gordon Hill) consisted of 122 hips with this same titanium fibre-mesh component (Harris-Galante Porous, Zimmer) 'press-fit' without any fixation screws. Hemispherical reamers were used to remove any remaining cartilage; routine removal of the subchondral plate was not performed. The component inserted was generally 2 mm larger than the nominal diameter of the last reamer used. Initial stability was obtained through a peripheral interference fit ('press-fit'). All femoral components were cementless and included 116 HGPs, 4 BIAS (Zimmer) and 2 AML (anatomic medullary locking) (DePuy, Warsaw, Indiana). The great majority of the heads were 28 mm. The average patient age was 67 years (ranging from 28 to 84). Follow-up ranged from 4 to 5.5 years with an average of 56 months [8].

Series 4 (surgeries performed by C.A.E.) consisted of 115 hips reconstructed with a solid, one-piece (non-modular), porous-coated cobalt-chrome acetabular component stabilized by three spikes (AML, DePuy, Warsaw, Indiana). Hemispherical reamers were used to prepare the acetabulum such that the outer diameter of the porous acetabular component was equal to the outer diameter of the last reamer used. All of the femoral components were non-modular and cementless (AML, DePuy). All of the heads were 32 mm. Follow-up ranged from 6 to 9 years with an average of 90 months [4].

Series 5 (surgeries performed by H.C.A.) consisted of 113 hips with a modular titanium fibre-mesh acetabular component with a unique chamfered cylinder design (CCD) (Zimmer, Warsaw, Indiana). This is the same porous coating technology as in Series 2 and 3. The first 35 of these CCD components (Series 5a) had a completely solid shell. The subsequent 78 had a single 8.5 mm pilot hole in the dome which allowed the surgeon to monitor 'seating' of the component during insertion (Series 5b). Special chamfered cylinder-shaped reamers were used to prepare the acetabulum. The cylindrical portion of the acetabulum was reamed 0.75 mm smaller than the outer diameter of the component to be inserted. The dome and chamfer sections were reamed to the same

dimensions as the component. This design is intrinsically stable through the peripheral interference fit. These were mated to femoral resurfacing components with head diameters from 38 to 51 mm (Porous Surface Replacement, or PSR, Zimmer). The average patient age was 54 years (ranging from 17 to 79). Follow-up ranged from 3.5 to 8 years with an average of 64 months [5].

Series 6 was a dual geometry titanium alloy acetabular component (Dual Geometry, Osteonics, Allendale, New Jersey) (surgeries performed by Dr Joseph Dimon). The dome of this component is hemispherical and the peripheral portion is cylindrical. The cylindrical diameter is 1 mm greater than the diameter of the dome portion. This component has multiple screw holes through the dome but was inserted without screws. Hemispherical reamers were used to prepare the acetabulum. The diameter of the dome portion of the inserted acetabular component was equal to the diameter of the last reamer used. The peripheral portion of the dual geometry component had a diameter 1 mm greater than the last reamer used. This design is intrinsically stable through the peripheral interference fit. All femoral components were modular and cemented (Omniflex, Osteonics). Twenty-nine heads were 32 mm and one was 28 mm. The average patient age was 60 years (ranging from 27 to 86). Follow-up was from 4 to 6 years with an average of 51 months.

Sequential anteroposterior radiographs were evaluated in all cases. The radiographic definition of osteolysis was consistent for all six series. Osteolysis was defined as radiographically apparent bone loss which has a non-linear, scalloped, erosive or balloon-like appearance. This type of bone loss does not follow the contours of the implant-bone interface but instead progresses away from the implant-bone interface into the pelvic bone(s) [5]. The incidence of pelvic osteolysis was determined using the most recent anteroposterior radiograph in each case.

3 RESULTS

In total, radiographs from 513 hips reconstructed with porous ingrowth acetabular components were reviewed. The shortest follow-up on any hip was 40 months. A summary of the data is presented in Table 1. A total of 45 pelvic osteolytic lesions were observed (8.8 per cent). Pelvic osteolysis was seen nearly as frequently in the ischium and pubis (21 lesions) as it was in the ilium (24 lesions).

There was no direct correlation between the presence of screw holes or screws and the incidence of pelvic osteolysis. In each comparison, the incidence of pelvic osteolysis was actually lower in the group assumed to be at increased risk (Table 2). The incidence of pelvic osteolysis around modular components with holes through the shell was 4.5 per cent (14 of 313 hips). The incidence of pelvic osteolysis with solid-shell components was 15.5

Table 1 Incidence of pelvic osteolysis with lesions by location

Series	Number	Average follow-up (months)	Most frequent head diameter (mm)	Cup	Screws	Incidence (%)	Ilium	Ischium	Pubis
1	50	85	26	Solid	+	4	1	0	1
2	83	68	26	Holes	+	1.2	1	0	0
3	122	56	28	Holes	-	0	0	0	0
4	115	90	32	Solid	-	14	12	2	5
5a	35	74	SR*	Solid	-	29	6	2	2
5b	78	59	SR*	Hole	-	12	3	6	2
6	30	51	32	Holes	-	6.7	1	1	0

*SR = surface replacement for head diameters ranging from 38 to 51 mm.

Table 2 Incidence of pelvic osteolysis

Holes	(14/313)	4.5%
No holes	(31/200)	15.5%
Screws	(3/133)	2.3%
No screws	(32/380)	11.1%
Modular	(24/348)	6.9%
One-piece	(21/165)	12.7%
Series 5b: hole	(11/78)	12.0%
Series 5a: solid	(10/35)	29.0%

per cent (31 of 200). The incidence of pelvic osteolysis around acetabular reconstructions with screws was 2.3 per cent (3 of 133). The incidence of pelvic osteolysis in reconstructions without screws was 11.1 per cent (32 of 380). The incidence of pelvic osteolysis in one-piece acetabular components (polyethylene pre-fixed in the metal shell) was 12.7 per cent (21 of 165) and the incidence of pelvic osteolysis with the modular components was 6.9 per cent (24 of 348).

The highest incidence of pelvic osteolysis was seen with the large diameter resurfacing components used in Series 5. Interestingly, the incidence of pelvic osteolysis was actually higher with the solid-shell version of this component (Series 5a; 29 per cent) than in the version with a dome pilot hole (Series 5b; 14 per cent). Further, six of the nine iliac lesions developed around the completely solid component. It should be noted that the average follow-up was 15 months longer for the solid-shell resurfacing components. An increased incidence of osteolysis (14 per cent) was also seen in Series 4, which had 32 mm heads and the longest average follow-up (90 months).

Series 1 utilized an acetabular component which was one-piece, solid and initially stabilized by multiple peripheral screws (ARC). Pelvic osteolysis developed in two hips (4 per cent). One lesion was in the ilium and one was in the pubis. Both components were radiographically well-fixed. Neither hip has been reoperated.

Pelvic osteolysis developed in one hip (1.2 per cent) in Series 2, which was reconstructed with the modular HGP acetabular component initially stabilized with multiple screws through the shell. This single lesion was in the ilium and developed around a fixation screw. This hip has been reoperated. The component was well-fixed

but the screw was loose. Tissue from around the screw contained titanium and polyethylene particles. There were no radiographically apparent pelvic osteolytic lesions in Series 3 where the modular HGP acetabular component, which has multiple holes through the shell, was press-fit without any screws.

The incidence of pelvic osteolysis in Series 4 (hips reconstructed with a non-modular, solid, acetabular component with three spikes, the AML component) was 14 per cent. There were twelve lesions in the ilium, two in the ischium and five in the pubis. The iliac lesions were not radiographically associated with the fixation spikes. The iliac lesions appeared to arise at the periphery of the component and were predominantly in Charnley zone 1. One hip with pelvic osteolysis has been reoperated. The component was well-fixed. Peripheral implant-bone interfacial resorption was contiguous with the cavitory bone loss in the ilium.

Pelvic osteolysis developed in 19 hips (17 per cent) from Series 5. The highest incidence of pelvic osteolysis (29 per cent) was seen in association with the modular acetabular component with a completely solid shell (Series 5a). Six of these ten lesions were in the ilium. The incidence of osteolysis in a similar component with a single pilot hole in the dome (Series 5b) was 14 per cent. Only three of these eleven lesions were in the ilium, six were in the ischium and two were in the pubis. Thus the incidence of iliac osteolysis was *higher* with the completely solid cup. Ten hips with pelvic osteolysis in Series 5 have been reoperated. The components were all well-fixed. In all cases a communication could be found through an area of bone resorption at the periphery of the implant-bone interface which led to osteolysis in the pelvis.

The incidence of osteolysis in Series 6, the dual geometry component, was 6.7 per cent. There was one lesion in the ilium and one in the ischium. One hip with pelvic osteolysis has been reoperated. This patient was only 27 years old. The hip had a small diameter acetabular component mated to 32 mm femoral head. There was extensive osteolysis of the proximal femur as well. The components were well-fixed. The initial thickness of the acetabular polyethylene was approximately 5 mm and had completely worn through. There was gross evidence

of peripheral acetabular bone resorption which communicated with the cavitary pelvic bone loss.

4 DISCUSSION

The finding of polyethylene particles in tissue adjacent to acetabular component screw holes and/or screws has been presented as evidence that the holes act as debris conduits or access channels [1-3]. It has also been suggested that the origin of retroacetabular polyethylene particles is the modular liner-shell interface and not the femoral-acetabular articulation. While such mechanisms are possible and may play a central role in iliac osteolysis with certain designs, the incidence data from these six series of acetabular reconstructions is not supportive of these being generic factors in the development of pelvic osteolysis.

Due to differences in the acetabular component designs and insertion techniques in these six series, this unique comparison addresses several of the issues in pelvic osteolysis. These issues include one-piece versus modular construction, solid shells versus shells with holes and fixation screws versus no screws. Based on this review, there was no relationship between the presence of screw holes or screws and the incidence of pelvic osteolysis. In fact, in each comparison the incidence of pelvic osteolysis was actually *lower* in the group assumed to be at increased risk.

An important realization is that pelvic osteolysis is not limited to the ilium. Pelvic osteolysis was seen nearly as frequently in the ischium and pubis (21 lesions) as it was in the ilium (24 lesions). Ischial and pubic osteolysis may not be explained by holes and/or screws through the acetabular component shell. On this basis alone, an alternative explanation of pelvic osteolysis with cementless acetabular components is needed.

Beuchel *et al.* [1] have reported a 40 per cent incidence of pelvic osteolysis which developed around 10 of 25 cementless hip resurfacing arthroplasties at a mean follow-up of only 3 years. The acetabular component was hemispherical, modular and had multiple holes for fixation screws. Radiographically, these lesions were adjacent to fixation screws directed into the ilium. Increased volumetric wear of the thin, large diameter, polyethylene acetabular liners was thought to be responsible for the liberation of excessive amounts of polyethylene debris. It was proposed that the debris may have gained access to the ilium through the screw holes.

In the present report, the highest incidence of pelvic osteolysis (17 per cent) was also seen with large diameter resurfacing components. The volumetric wear rate of these polyethylene components is 4-10 times higher than a 28 mm component [5, 9]. Interestingly, the incidence of pelvic osteolysis (29 per cent) was actually higher in the solid-shell version of this component (Series 5a) than in the version with a dome pilot hole (Series 5b; 15 per

cent). Further, six of the nine iliac lesions developed around the completely solid component. This indicates that pelvic, and more specifically, iliac, osteolysis can occur in the absence of any holes through the acetabular component shell. Observations made at the time of reoperation for femoral side failure of these resurfacing components indicate that wear debris can gain access to the cancellous bone behind an acetabular component through defects in the peripheral implant-bone interface [10].

With regard to conventional (stemmed) total hip replacements, an increased incidence of osteolysis (14 per cent) was seen in Series 4. This component was non-modular with a completely solid shell. This series had exclusively 32 mm heads and the longest average follow-up (90 months) of the six series. Pelvic osteolysis appears to be related to larger diameter bearing surfaces (especially when combined with thin polyethylene) and longer follow-up. Fundamental variables in the pathogenesis of pelvic osteolysis include the rate and/or total *amount* of polyethylene wear particles generated and *access* of these particles to bone. Volumetric wear is the important clinical wear variable because the number of polyethylene particles generated is related to the volumetric wear. Volumetric wear of polyethylene increases with the number of gait cycles (the amount of use) and the square of the radius of the bearing surfaces. For the same number of cycles, there is a 7-9 per cent increase in the volumetric wear of polyethylene for every 1 mm increase in the diameter of the bearing [11]. Increased volumetric wear has been identified as a disadvantage of 32 mm femoral heads in total hip replacements [12, 13]. Because of the large diameter bearing surface and active patients, hip resurfacing arthroplasty is a clinical model of the adverse consequence of very high volume polyethylene wear [5].

The size, morphology and number of polyethylene wear particles are determined by the wear mechanism(s) that generates them [10, 14, 15]. The numerous very small, often submicrometre sized, polyethylene particles associated with bone resorption in total hip replacements are a result of a specific wear mechanism: the polished femoral head moving against the highly conforming acetabular polyethylene bearing over a relatively long sliding distance [16]. Wear does occur between the modular polyethylene liner and the metal shell. However, the volume of material is less than that generated at the femoral-acetabular articulation and the polyethylene particles produced at the liner-shell interface are different (fewer and larger) due to substantial differences in wear mechanisms [14].

Particle access to bone has been modelled by the concept of the *effective joint space*, which includes all periprosthetic regions in communication with joint fluid and particulate wear debris [17]. In the effective joint space, joint fluid and wear debris will follow the path of least resistance and focal accumulation is associated with

osteolysis [5, 17]. Bone resorption *along the interface* is commonly seen with acetabular components fixed with cement, and this process can result in component loosening [18]. Pelvic osteolysis in these cementless cases occurs around well-fixed components. Compared to an acetabular cement-bone interface, porous ingrowth acetabular components may offer increased resistance to the ingress of joint fluid and wear debris. With a porous-coated acetabular component, the path of least resistance may be into the soft, porous and cellular cancellous bone and marrow of the pelvis rather than into an extensively ingrown implant-bone interface. The majority of the bone resorption around a well-fixed cementless acetabular component thus progresses *away from the interface* into the soft cancellous bone of the pelvis [5]. A screw which penetrates into the cancellous bone of the pelvis can create an access channel. However, if the screw osseointegrates the path is effectively eliminated [19].

In addition to the incidence data, intraoperative observations and tissue samples indicate that, regardless of other acetabular component design features, a generic route of joint fluid and polyethylene wear debris to the bone behind the component is from the femoral-acetabular articulation through regions of the peripheral implant-bone interface without sufficient contact or ingrowth [5-8, 17]. This peripheral access is similar to what has been demonstrated for cemented acetabular components [18] and can result in iliac osteolysis behind well-fixed cemented acetabular components [20, 21].

Improvements in modular acetabular component design can minimize the generation of particulate debris. Avoiding the routine use of acetabular fixation screws avoids the risk of vascular injury as well as reducing the potential mechanisms of particle generation. Reduction or elimination of holes in the acetabular shell increases the strength of the shell and increases the surface area available for bone ingrowth. A solid shell potentially allows more uniform stress distribution and support of the polyethylene. However, the present data indicate that elimination of holes and/or screws through the acetabular shell will not eliminate pelvic osteolysis. The development of pelvic osteolysis is multifactorial and includes the total volumetric wear of polyethylene as well as *specific features* of the acetabular reconstruction (the component and the insertion technique) which determine the major access routes of fluid and debris to pelvic bone.

ACKNOWLEDGEMENTS

The authors acknowledge and thank Dr Gordon Hill for contribution of Series 3 cases to this study and Dr Joseph 'Skoot' Dimon for contribution of Series 6 cases to this study. The work was supported by the William H. Harris Foundation and the Los Angeles Orthopaedic Foundation.

REFERENCES

- 1 Buechel, F. F., Drucker, D., Jasty, M., Jiranek, W. and Harris, W. H. Osteolysis around uncemented acetabular components of cobalt-chrome surface replacement hip arthroplasty. *Clin. Orthop.*, January 1994, 298, 202-211.
- 2 Huk, O. L., Bansal, M., Betts, F., Rimnac, C. M., Lieberman, J. R., Huo, M. H. and Salvati, E. A. Polyethylene and metal debris generated by non-articulating surfaces of modular acetabular components. *J. Bone Jt Surg.*, 1994, 76-B, 568-574.
- 3 Maloney, W. J., Peters, P., Engh, C. A. and Chandler, H. Severe osteolysis of the pelvis in association with acetabular replacement without cement. *J. Bone Jt Surg.*, November 1993, 75-A, 1627-1635.
- 4 Beauchet, R. P., Engh, C. A. and Schmalzried, T. P. Roentgenographic evaluation of the AML porous-coated acetabular component: a six-year minimum follow-up study. *Orthop. Trans.*, 1992, 16, 318.
- 5 Schmalzried, T. P., Guttman, D., Grecula, M. and Amstutz, H. C. The relationship between the design, position, and articular wear of acetabular components inserted without cement in the development of pelvic osteolysis. *J. Bone Jt Surg.*, May 1994, 76-A, 677-688.
- 6 Schmalzried, T. P. and Harris, W. H. The Harris-Galante porous-coated acetabular component with screw fixation: radiographic analysis of eighty-three primary hip replacements at a minimum of five years. *J. Bone Jt Surg.*, 1992, 74-A, 1130-1139.
- 7 Schmalzried, T. P. and Harris, W. H. The hybrid total hip replacement: a six and one half-year follow-up study. *J. Bone Jt Surg.*, 1993, 75-B, 608-615.
- 8 Schmalzried, T. P., Wessinger, S. A., Hill, G. E. and Harris, W. H. The Harris-Galante porous (HGP) acetabular component press-fit without screw fixation: five-year radiographic analysis of primary cases. *J. Arthroplasty*, 1994, 9, 235-242.
- 9 Kabo, J. M., Gebhard, J. S., Loren, G. and Amstutz, H. C. *In vivo* wear of polyethylene acetabular components. *J. Bone Jt Surg.*, 1993, 75-B, 254-258.
- 10 Schmalzried, T. P., Jasty, M., Rosenberg, A. and Harris, W. H. Polyethylene wear debris and tissue reactions in knee as compared to hip replacement prostheses. *J. Appl. Biomater.*, 1994, 5, 185-190.
- 11 Clarke, I., Gustafson, A. G. N., Fujisawa, A. and Jung, H. Effects of femoral-head diameter on polyethylene wear rates *in vitro*. Presented at the Sixty-First Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, Louisiana, 28 February 1994.
- 12 Livermore, J., Ilstrup, D. and Morrey, B. Effect of femoral head size on wear of the polyethylene acetabular component. *J. Bone Jt Surg.*, 1990, 72-A, 518-528.
- 13 Morrey, B. F. and Ilstrup, D. Size of the femoral head and acetabular revision in total hip-replacement arthroplasty. *J. Bone Jt Surg.*, 1989, 71-A, 50-55.
- 14 Guttman, D., Schmalzried, T. P., Kabo, J. M. and Amstutz, H. C. Surface characterization, back-side wear and volumetric wear of acetabular polyethylene liners. *Trans. Orthop. Res. Soc.*, 1994, 19, 178.
- 15 Schmalzried, T. P., Campbell, P., Brown, I., Schmitt, A. K. and Amstutz, H. C. Shapes and dimensional characteristics of polyethylene wear particles generated *in vivo* by total

- knee replacements compared to total hip replacements. *J. Biomed. Mater. Res. (Appl. Biomater.)*, 1997, 38, 203-210.
- 5 McKellop, H. A., Campbell, P., Park, S., Schmalzried, T. P., Grigoris, P., Amstutz, H. C. and Sarmiento, A. The origin of sub-micron polyethylene wear debris in total hip arthroplasty. *Clin. Orthop.*, 1995, 311, 3-20.
- 1 Schmalzried, T. P., Jasty, M. and Harris, W. H. Periprosthetic bone loss in total hip arthroplasty: the role of polyethylene wear debris and the concept of the effective joint space. *J. Bone Jt Surg.*, 1992, 74-A, 849-863.
- 1 Schmalzried, T. P., Kwong, L. M., Jasty, M., Sedlacek, R. C., Haire, T. C., O'Connor, D. O., Bragdon, C. R., Kabo, M., Malcolm, A. and Harris, W. H. The mechanism of loosening of cemented acetabular components in total hip arthroplasty: analysis of specimens retrieved at autopsy. *Clin. Orthop.*, 1992, 274, 60-78.
- 19 Pidhorz, L. E., Urban, R. M., Jacobs, J. J., Sumner, D. R. and Galante, J. O. A quantitative study of bone and soft tissues in cementless porous-coated acetabular components retrieved at autopsy. *J. Arthroplasty*, 1993, 8, 213-225.
- 20 Charnley, J. *Low Friction Arthroplasty of the Hip*, 1979 (Springer-Verlag, New York).
- 21 Pierson, J. L. and Harris, W. H. Extensive osteolysis behind an acetabular component that was well fixed with cement. *J. Bone Jt Surg.*, 1993, 75-A, 268-271.

Charnley wear model for validation of hip simulators—ball diameter versus polytetrafluoroethylene and polyethylene wear

J C Clarke¹, V Good¹, L Anissian² and A Gustafson²

¹Howard and Irene Peterson Tribology Laboratory, Loma Linda University Medical Center, Loma Linda, California, United States of America

²Department of Orthopedics, Loma Linda University Medical Center, Loma Linda, California, United States of America

Abstract: Wear rates of polytetrafluoroethylene (PTFE) and polyethylene cups were compared in 9-channel and 12-channel simulators, using serum lubrication and gravimetric techniques for wear assessment. Cobalt-chromium (CoCr) and alumina ceramic femoral heads in 22–42 mm diameter range were used to validate simulator wear rates against clinical data. This was also the first study of three femoral head sizes evaluated concurrently in a simulator (with three replicate specimens) and also the first report in which any wear experiments were repeated. Fluid absorption artefacts were within ± 1 per cent of wear magnitude for PTFE and ± 8 per cent for polyethylene and were corrected for. Wear rates were linear as a function of test duration. Precision within each set of three cups was within ± 6 per cent. The wear rates from experiments repeated over 15 months were reproducible to within ± 24 per cent. However, the magnitudes of the simulator wear rates were not clinically accurate, the PTFE wear rates ($2843 \text{ mm}^3/10^6$ cycles; 22 mm diameter) were over three times higher than *in vivo*, the polyethylene 30 to 50 per cent on the low side ($23 \text{ mm}^3/10^6$ cycles; 22 mm diameter). Volumetric wear rate increased with respect to size of femoral head and a linearly increasing relationship of 7–8 per cent/mm was evident with respect to femoral head diameter for both PTFE and polyethylene. These data compared well with the clinical data.

Keywords: hip simulator, wear, head diameter, polyethylene, polytetrafluoroethylene, cup

NOTATION

- D_a diameter of experimental femoral head A
- D_r diameter of reference head (Charnley 22.25 mm)
- V_a volumetric wear of experimental femoral head A
- V_r volumetric wear of reference head (Charnley 22.25 mm)

1 INTRODUCTION

In an early review of laboratory wear studies, Swanson commented that 'no significant feature of current practice had been based on results obtained in simulators' (1). Almost 20 years following Swanson's review, there is still controversy over simulator design, whether to use

water or biological fluids as the lubricant of choice, and whether dimensional or weight loss methods of wear assessment are even adequate for the task. Certainly, the pioneering simulator test protocols had considerable limitations, particularly with a test capacity limited to one implant per machine (2–4). This limited the evaluation of polyethylene wear, which required two to three months to complete the necessary 2 to 3 million cycles. Thus, to run three specimens each for only two test parameters would require the demanding task of running six tests of duration 12 to 18 months. This raised the additional question as to whether such tests would even be reproducible from month to month. Ideally, all pertinent wear data should be acquired during one test run. This requires multi-channel test capacity per machine.

Contemporary laboratory wear studies from Europe have featured simulators with a test capacity of two to five hip implants (Table 1). However, even 5-channel machines require repeated test runs to complete replicate

The MS was received on 15 January 1996 and was accepted for publication on 22 April 1996.

Table 1 Summary of simulator design features, reported polyethylene wear rate magnitudes and ranking of head diameter with respect to wear rate (SG = simulated gait cycle; sine = sinusoidal load profile)

Study	Head material	Diameter (mm)	Test stations	Data set	Load type	Peak load (kN)	Lubricant	Wear ($\text{mm}^3/10^6$ cycles)	Diameter ranking
Wright and Scales (3)	CoCr	25, 32	1	No	SG	1.4	Serum	30-70	32 < 25
McKellop and Clarke (9)	CoCr	32	10	Yes	SG	2.4	Serum	37-114 (79)	
Saikko (27)	CoCr	32	5	No	SG	3.5	Water	0.4-174	
McKellop <i>et al.</i> (15)	316SS	22, 28	10	Yes	SG	2	Serum 90%	41-55	22 < 28
McKellop <i>et al.</i> (12)	316SS	32	10	Yes	SG	2	Serum 90%	26-48	
Pappas <i>et al.</i> (18)	CoCr	32	5	No	SG	2.2	Water (spray)	56	47 < 32
Saikko (19)	CoCr	28	5	No	SG	3.5	Water	72-153	
Clarke <i>et al.</i> (6)	Alumina	22, 26, 28	9	Yes	Sine	2	Serum 90%	23-33	22 < 26 < 28
Derbyshire <i>et al.</i> (37)	Zirconia	22, 26, 32	2	No	SG	3	Water	10-132	22 < 26 < 32
McKellop <i>et al.</i> (12)	Alumina	32	10	Yes	SG	2	Serum 90%	27-58	
McKellop <i>et al.</i> (12)	Zirconia	32	10	Yes	SG	2	Serum 90%	20-26	
Saikko (19)	Zirconia	28, 32	5	No	SG	3.5	Water	0-28	Unimportant

Table 2 Wear model derived from clinical retrievals of PTFE cups (7). Linear regression data used to calculate the corresponding wear values for the four head diameters

Linear regression trend	Head diameter (mm)	Wear range ($\text{mm}^3/10^6$ cycles)	Gradient (mm^3/mm)	R^2	VWI (mm^3/mm)	Wear rates from linear regression		
						22.25 mm	28 mm	38 mm
X	22-28	880-1140	41.1	0.9996	4.7%	880	1116	1527
Y	22-42	880-1900	54.3	0.9941	6.4%	844	1157	1700
Ratio Y/X			1.32		1.36	0.96	1.04	1.11
								1.13

tests. In contrast, the hip simulators developed in the United States have had 9, 10 or 12 test stations which permitted simultaneous testing of three replicate implants for three to four design variables per test (5, 6). Such simulators allow for greater flexibility in experimental design plus quantification of precision and accuracy using replicate implants. For example, this capacity now permits testing of multiple diameters of femoral heads at the same time on one machine. One can clearly see the contradictions in the historical record with regard to this one important design variable (Table 1). Two studies found that the least volumetric wear resulted from larger head sizes (32 mm, 47 mm) and three studies indicated the smallest size (22 mm). The most recent study reasoned that ball size (28 versus 32 mm) seemed an unimportant variable because zero wear was apparent with both sizes of zirconia heads tested in water.

In terms of validating simulator wear performance against a clinical standard, the size of the femoral head should play a key role in scientific studies. In the authors' opinion, the definitive clinical statement on head size versus wear was issued by Charnley from his analysis of retrieved polytetrafluoroethylene (PTFE) acetabular cups (7). Charnley noted that volumetric wear increased with diameter from 880 mm³/year for the 22.25 mm head size up to 1900 mm³/year for the 41.5 mm size (Fig. 1a). Inspection of his PTFE data in the 22–28 mm range indicated that there was a virtually linear relationship with regard to head size, with annual rates of wear increasing at 41 mm³ per millimetre increase in head size (6, 8). These data (Fig. 1b) appeared to be an excellent clinical model with which to validate simulator test protocols (Table 2).

The aim of this study was to investigate the precision, accuracy and repeatability of simulator wear data using polyethylene and PTFE cup materials. Four sizes of femoral head were selected to study the ball size effects predicted by Charnley. Other variables included choice of ceramic (Al₂O₃) or metal (CoCr) femoral heads, serum lubrication and use of the weight loss technique for wear assessment.

2 METHODS

Beginning in 1990, the principal author (ICC) conceived a multi-channel simulator concept that would be relatively inexpensive, have all operating systems mounted in a closed cabinet below the wear stations for protection of the implants and provide the operator with ease of access for quick dismounting of multiple wear and soak control implants. Also included in the design was the flexibility to add other features as the research progressed.

In collaboration with Shore Western Manufacturing Incorporated, (SWM, Monrovia, California, United States), the basic simulator machine was designed as

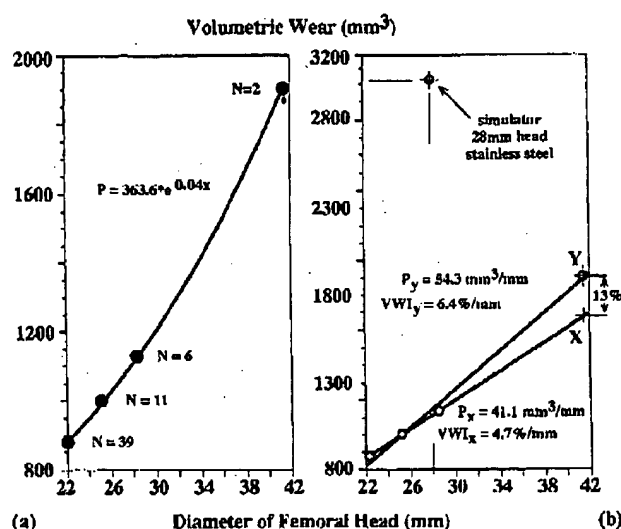


Fig. 1 Wear model calculated from Charnley's pioneering data for PTFE volumetric wear relative to head size (22.25, 25.25, 28.5 and 41.5 mm). The data came from those cups which had not worn through (7)

- Exponential curve appeared to provide a good fit for the volumetric wear values relative to the four head sizes. Wear penalty gradient P , given by $P = 363.6 e^{0.04x}$ (x = head size, N = number of cases)
- The Charnley PTFE wear data compared to average data from a simulator study of 28 mm stainless steel heads on PTFE cups (9). The simulator data was three times higher than the *in vivo* rates measured by Charnley (scale reduced from Fig. 1a). Trend line X is the linear regression analysis for Charnley data in the 22.25–28 mm range whereas trend line Y included the 42 mm data. Trend line X appeared a better model not only because of more data available ($R^2 = 0.9996$; $N_{22} = 39$; $N_{42} = 2$) but also the 22–28 mm range reflected contemporary head sizes

simply as possible, on the top deck for ease of access, for simple specimen assembly and to minimize the possibility of contamination by oil from the hydraulic actuators (Fig. 2). The majority of previous simulator studies had been conducted with three specimen replicates per wear set (9). Therefore, modules of six, nine and twelve wear cup stations were selected for the new simulator configuration. Each tower held three wear stations and each ball and cup unit could be retrieved by unlocking one clamp. Plastic hoods also helped to shield each load tower from air-borne contaminants.

The rotating cam principle for incorporating cup motion had clearly withstood the test of time (9). The cup chambers were mounted on bearing blocks to represent the typical flexion angle between cup and hip joint



Fig. 2 SWM wear machine

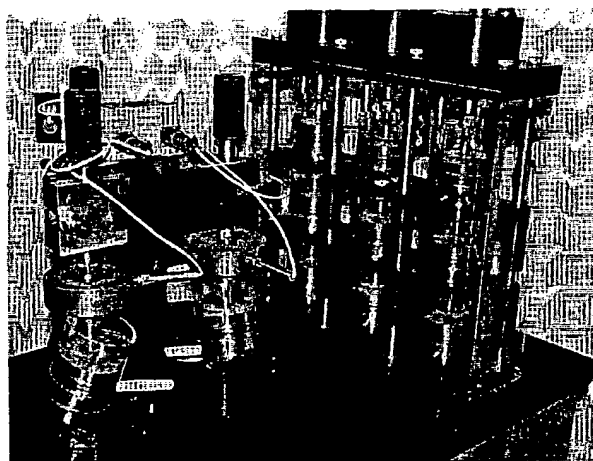


Fig. 3 SWM wear station

load axis. The rotating cams (uni-directional) carrying the specimen chambers were belt driven by an electric motor at 1 Hz frequency. For this study, the cam rotation was not synchronized with the hip joint loading (Fig. 3). Clutches allowed for disengaging any combination of test stations. All load actuators worked off one servo-hydraulic valve and the resulting pressure was displayed by monitor, chart recorder or oscilloscope.

Experience with three developments of the SWM simulators has been obtained to date (Table 3). The first SWM 9.0 simulator was used for the polyethylene wear study with three sizes of alumina ceramic femoral heads (22.25, 26 and 28 mm) and non-loaded soak controls (6). Load magnitudes for the sinusoidal profiles were set manually on the function generator and monitored via oscilloscope. The second simulator was basically the same machine but with the addition of three banks of load frames for nine dynamic soak control stations (SWM 9.9). The soak control cups experienced identical dynamic load profiles but no articulation. This machine provided the majority of the PTFE wear data (8). The

following parameters were added sequentially during the development phase of the SWM 9.9 simulator:

- (a) cup self-centring on load axis;
- (b) frictional torque sensors;
- (c) capability for anatomical cup positioning;
- (d) computer control of load profiles.

The third machine incorporated 12 wear channels (10), improved specimen fixturing features and upgraded software functions (SWM 12.12). In addition, both the anti-rotation peg and the friction sensor pegs were guide-mounted on rollers to provide continuous constraint.

In August 1994, the Howard and Irene Peterson Tribology Laboratory was created at Loma Linda University Medical Centre and installed the first SWM simulator. The initial goal of this laboratory was to examine the effects on wear of basic parameters involved in simulator design and test protocols. Femoral head size was considered to be a very significant clinical variable (7, 11). Alumina femoral heads were selected because their superior surface finish would remain unchanged during the testing (ATH design, 22 mm, 26 mm and 28 mm heads; Kyocera Incorporated, Kyoto, Japan).

The polyethylene cups were arranged facing upwards (non-physiological) in the SWM 9.0 simulator which did not have a self-alignment device, frictional torque sensors or lubricant temperature control. All tests were run at 2 kN peak load with sinusoidal load profile. A solution of 90 per cent bovine serum was used as the lubricant [10 per cent standard additives of sodium azide and EDTA reference number (12)]. The specimen chambers were replenished with distilled water during the tests. The density of the 415-GUR polyethylene cups (0.931 mg/mm^3) was used to convert the cup weight data to volumetric wear rates. The cups were not sterilized prior to testing.

Polytetrafluoroethylene acetabular cups were machined from extruded bar stock (ASTM D-1710). The specific density of PTFE was taken as 2.16 representing the mid-range value in the material certification. Three PTFE wear cups and one soak control cup were used per head size. The soak control cups were stored unloaded in de-ionized water. Matching alumina ceramic femoral heads (22.25, 28, 38 and 42 mm diameters) were provided by Cerasiv Incorporated (Plochingen, Germany) and CoCr femoral heads (22.25, 28, and 42 mm diameters) from Protek Incorporated (Berne, Switzerland). The diametrical clearance between cups and femoral heads ranged from 0.3 to 0.5 mm. The PTFE cups were arranged facing upwards (non-anatomical) in two multi-channel hip simulators (SWM 9.9, SWM 12.12). The cup-ball alignment was fixed (no self-centring device) for tests up to HE021 and then self-centring from HE022 onwards. Lubricant used for all PTFE tests was 100 per cent bovine serum (Hyclone Laboratories, Logan, Utah, United States). All 9-channel tests were run at 2 kN peak load with sinusoidal load profile; the 12-channel tests were run at 2 kN

Table 3 Development of SWM simulators in Howard and Irene Peterson Tribology Laboratory, Loma Linda University Medical Center

	Simulator type		
	SWM 9.0	SWM 9.9	SWM 12.12
Wear stations	9	9	12
Soak stations	None	9	12
Temperature control	None	None	None
Recirculating fluid	None	None	None
Lubricant	Serum + additives	Varied	Varied
Self-align axis	None	Added	Yes
Friction torque	None	Added	None
Torque-peg guide	None	None	Yes
Cam angle	23°	23°	20°
Cam bearings	Manual lubrication	Manual lubrication	Self-lubricating
A/Rotation peg	Cup base	Cup base	Ball centre
A/Rotation peg guide	None	None	Yes
Cup orientation	Inverted	Invert/anatomical	Inverted
Load controller	Manual	Computer added	Computer
Load profile	Sinusoidal	Sine/Paul	Sine/Paul
Drive clutches	Yes	Yes	Yes
Rotation	Unidirectional	Unidirectional	Variable
Load motion	Non-synch	Non-synch	Non-synch
Ball diameter (mm)	22, 26, 28	22, 28, 32, 38, 42	22, 28, 32, 35, 38, 42

peak load with the Paul gait curve. Lubricant temperatures were monitored but not controlled. The specimen chambers were replenished with serum during the tests.

Polyethylene wear was determined by the weight loss method using a microbalance (Sartorius RC 210S) which communicated directly with a desktop computer (Macintosh 8100). Wear and soak specimens were cleaned and dehydrated together, each set being re-weighed two to four times in order, and a 32 mm CoCr femoral head was used at each weighing as a microbalance calibration standard.

With regard to the relationship between test duration (cycles) and volume of wear, the overall volumetric wear rate was determined by the slope of the linear regression line (all data from the three cup set). A consistent wear rate, i.e. gradient of the linear regression trend, was deemed more significant than the actual magnitude of the wear at any point in time. The 95 per cent confidence interval was used to estimate the variation in linear regression wear rates. The linear regression trend was also determined for each cup and the resulting 'scatter' calculated to detect any aberrant wear behaviour in each set. This simple term also provided an estimate of variation in published wear rates where generally only two to five wear rate values were given

Scatter (maximum or minimum) %

$$= \frac{100 \times (\text{maximum value} - \text{average value})}{\text{average value}}$$

The average wear rate $\pm 2 \times$ standard deviations (2 S.D.) was used to estimate the variation for the repeated PTFE experiments.

With regard to the relationship between ball size and volumetric wear rates, the wear penalty (P mm³/mm)

was taken as the slope of the linear regression line per millimetre increase in ball size. The volumetric wear index (VWI) was a dimensionless quantity used to relate the percentage wear increase of any size of femoral head relative to the 22.25 mm reference size. The VWI ratio for femoral head size A was calculated from the equation

$$\text{VWI (\% per millimetre)} = \frac{100 \times (V_a - V_c)/V_c}{(D_a - D_c)}$$

where

V_a = volumetric wear of femoral head A

V_c = volumetric wear of reference head (Charnley 22.25 mm)

D_a = diameter of femoral head A

D_c = diameter of reference head (Charnley 22.25 mm)

Following the wear tests, samples of the debris from the PTFE and polyethylene implants were analysed both at the Joint Replacement Institute, Orthopedic Hospital, Los Angeles and at Loma Linda University Medical Centre. In addition, the wear debris was collected and compared to data from retrieved ATH implants (13, 14).

3 RESULTS

The PTFE material demonstrated a wear range from 1500 to 9470 mm³/10⁶ cycles whereas the polyethylene range was only 23–33 mm³/10⁶ cycles (Table 4). In general, the wear trends from the PTFE and polyethylene studies appeared remarkably consistent, despite their great difference in wear magnitudes. The three cups in each wear set generally tracked in a linear and essentially parallel manner throughout the test duration (Figs 4a and 5a). The PTFE soak trends varied from positive to

Table 4 Summary of PTFE and polyethylene experiments. The PTFE cup data represented 2544 weighings (average number per experiment = 320) and the polyethylene cups 360 in total. The experiment HE002 exhibited PTFE wear rates which were remarkably different from the other experiments and was excluded from the analysis

Experiment	Dates	Ball/cup	Number of events	Cycles	Diameter (mm)	Wear rates			Variation (\pm %)	Slope P (mm ³ /mm)	VWI (%/mm)
						(mm ³ /Mc)	CL - 95	CL + 95			
HE002	August 94	CoCr/PTFE	3	24 K 2 0.987	22.25 28 42	1515 2334 6291	1668 2935 6924	1363 1714 5657	10.1 26.6 10.1	142	9.4
HE004	August 94	CoCr/PTFE	4	24 K 3 0.987	22.25 28 42†	2985 4632 8416	2946 4518 8070	3025 4746 8761	1.3 2.5 4.1	286	9.6
HE015	January 95	CoCr/PTFE	8	115 K 7 0.995	22.25 28 42	2952 4779 8430	2871 4648 8293	3034 4910 8567	2.7 2.7 1.6	318	10.8
HE014	January 95	Al ₂ O ₃ /PTFE	4	103 K 4 0.998	22.25 28 42	3257 4469 8442	3153 4365 8146	3361 4572 8739	3.2 2.3 3.5	211	6.5
HE022	March 95	Al ₂ O ₃ /PTFE	8	46.6 4 0.997	22.25* 28 42	2401 3428 7418	2259 3329 7299	2453 3526 7536	5.6 2.9 1.6	179	7.4
HE032	June 95	Al ₂ O ₃ /PTFE	6	75.3 K 5 0.999	22.25 28 42	2949 3987 6453	2866 3781 6100	3032 4194 6806	2.8 5.2 5.5	181	6.1
HE038	August 95	Al ₂ O ₃ /PTFE	9	57.4 K 6 0.995	22.25* 28† 38†	2620 4036 6409	2499 3902 6143	2741 4169 6676	4.6 3.3 4.2	246	9.4
HE045	November 95	Al ₂ O ₃ /PTFE	7	134 K 6 0.998	22.25* 28 38	2740 4261 6837	2670 4094 6635	2809 4429 7039	2.6 3.9 3.0	265	9.7
HE005	1993	Al ₂ O ₃ /PE	10	1092 K 5 0.984	22.25 26 28	23.2 31.9 32.8	22.0 30.7 31.8	24.4 33.1 33.8	5.3 3.8 3.2	1.75	7.40

Data includes overall (a) minimum number of cycles represented in the linear regression analysis; (b) minimum number of wear events included; (c) minimum value of R^2 (regression coefficient). The abbreviation CL denotes confidence limits from linear regression. Variation about wear average = (95CL - average)/average. Wear sets with data variation greater than 6 per cent (regression coefficient $R^2 < 0.988$) had either a break-away wear cup (*), or the first few data points were inconsistent with the later dominant wear trend (†). In the former case, the break-away implant data were eliminated. In the latter case, the early data points were removed from the set.

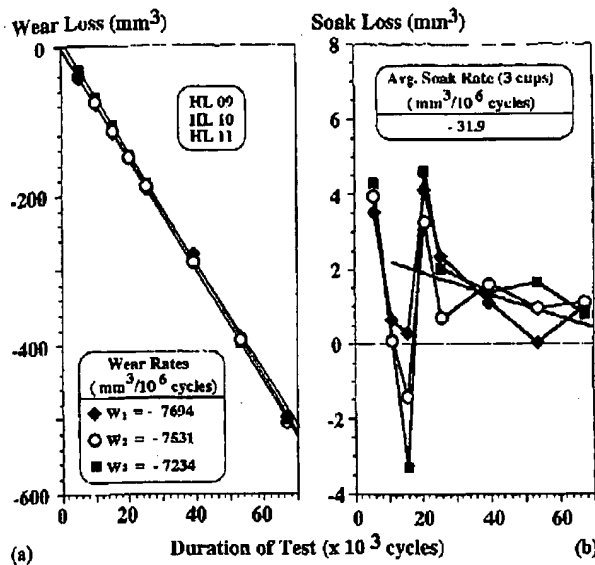


Fig. 4 Change in volumetric wear with regard to test duration for PTFE wear cup set articulating with 42 mm alumina femoral heads (HE022: seven events spanning 67 000 cycles)

- The three individual wear trends provided an average rate of $7486 \text{ mm}^3/10^6 \text{ cycles}$ with scatter ± 3.4 per cent. Negative slope denoted that this was observed as a weight loss. Linear regression for the entire data set provided an overall wear rate of $7418 \text{ mm}^3/10^6 \text{ cycles}$ with ± 1.6 per cent variation (95 per cent confidence limits)
- The three soak cups demonstrated an overall soak rate of $-31 \text{ mm}^3/10^6 \text{ cycles}$. Negative slope denoted that this was also observed as a weight loss. Note that the scale is 50 times magnified compared to Fig. 4a

negative slopes but the soak magnitudes were always less than 1 per cent of the wear magnitudes (Fig. 4b). The polyethylene soak trends were positive once they attained their stable sorption performance and such trends were always less than 8 per cent of the polyethylene wear magnitudes (Fig. 5b). Both phenomena were corrected for during the data analysis.

There were a few exceptions to the consistent and linear wear tracking behaviour. In three experiments, the first one or two data points were deleted from the linear regression analysis because the subsequent wear trend had a consistently greater gradient (Fig. 6). Also, in two PTFE and one polyethylene experiment, one of the three cups in each wear set showed some deviation from the other two (Fig. 6). This was generally observed as a decrease in wear rate during one or more wear events. The break-away specimen resumed parallel to the other two wear tracks during subsequent wear events. When the deviant cup was included, the variation per set was in the ± 10 per cent range. For this study, the break-away cup's data were deleted from the set. This increased

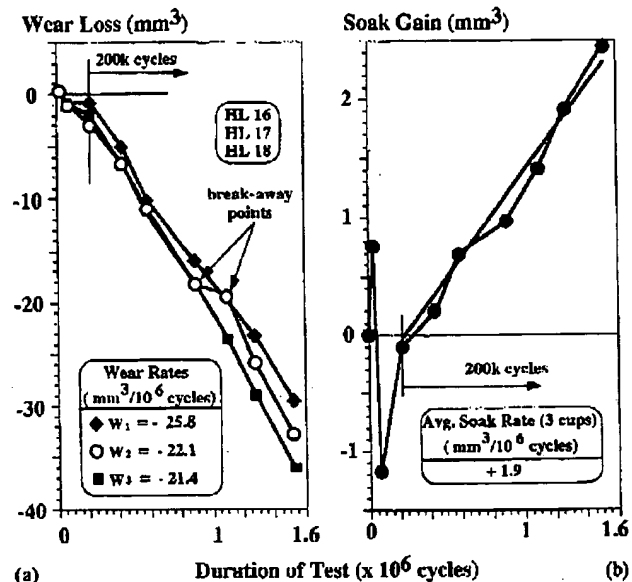


Fig. 5 Change in volume of polyethylene cup sets articulating with 22.25 mm alumina femoral heads (HE005: eight wear events spanning 1.53 million cycles)

- The three wear trends represented an average wear rate of $-23 \text{ mm}^3/10^6 \text{ cycles}$ with ± 5 per cent variation (95 per cent confidence limits). Negative slope denoted that this was observed as a weight loss. Using only the consistent data at 200 000 cycles and beyond increased the average wear rate by 6 per cent; dropping break-away specimen IIL017 raised the average wear rate by an additional 2 per cent
- Soak cups demonstrating consistent behaviour beyond 200 000 cycles with positive soak rate of $1.9 \text{ mm}^3/10^6 \text{ cycles}$. Note that the scale in Fig. 5b is ten times magnified compared to Fig. 5a

the average wear rates by 7 per cent for HE045 and 21 per cent for HE038 and brought their variation to within ± 5 per cent (Table 4).

All experiments demonstrated increased wear with respect to head size. The average wear rates for PTFE varied from a low of $1515 \text{ mm}^3/10^6 \text{ cycles}$ average (HE002) for a 22.25 mm diameter head to a high of $9467 \text{ mm}^3/10^6 \text{ cycles}$ for a 42 mm diameter head. In one experiment (HE002), the wear data consistently varied from 20 to 50 per cent less than the other seven experiments and was excluded from subsequent analysis (Table 4). The wear rates for the seven PTFE experiments averaged 2843, 4227 and $8192 \text{ mm}^3/10^6 \text{ cycles}$ (2 S.D. = ± 24 per cent) for 22.25, 28 and 42 mm diameters, respectively (Table 5). The wear penalty (gradient P) for the linear trends in the 22–28 mm diameter range varied from $179 \text{ mm}^3/\text{mm}$ to $317 \text{ mm}^3/\text{mm}$ (Fig. 7) and

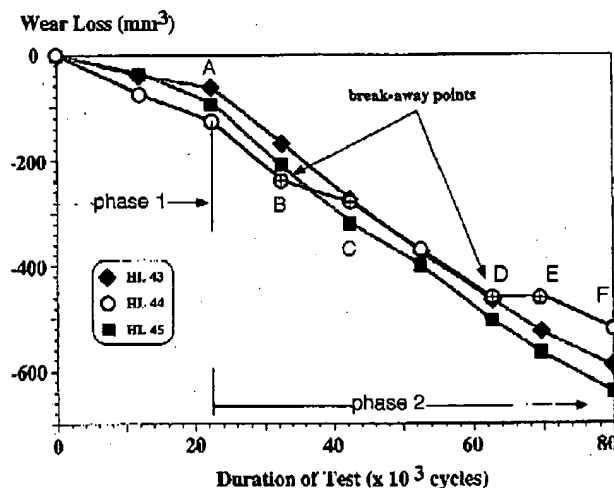


Fig. 6 Wear trend in PTFE experiment could be separated into two phases (HE038, 42 mm alumina heads with 80 000 cycles). Phase 1 had the lowest wear rate and duration 22 000 cycles; phase 2 had a consistently higher rate for the duration of the experiment. Wear track for cup HL044 deviated from the other two at point B, then resumed to track parallel to them between points C and D, only to break away again from D to E

Table 5 Overall statistics for seven PTFE experiments involving 9-channel (5) and 12-channel (2) simulators. Linear regression fit for 22–38 mm head range provided wear penalty of $240 \text{ mm}^3/10^6 \text{ cycles}$ ($R^2 = 0.9999$) and VWI of 8.5 per cent. Accuracy ratio compares the average PTFE values to the clinical model from Charnley's data (Table 2)

	Diameter (mm)			
	22.25	28	38	42
Average wear rate	2843	4227	6623	8192
2 S.D.	560	917	NA	1949
Variation (2 S.D.)	20%	22%	NA	24%
Penalty ($P \text{ mm}^3/\text{mm}$)	$240 \pm 44\%$			
VWI (%/mm)	$8.4\% \pm 43\%$			
Accuracy ratio	3.2	3.8	4.5	4.8

the corresponding VWI values from 6.1 to 10.8 per cent/mm (Table 4).

The average PTFE data from the two 12-channel experiments showed an excellent linear fit ($R^2 = 0.9999$) for the 22–38 mm data range (Fig. 7). These provided average values for wear penalty of $250 \text{ mm}^3/\text{mm}$, a VWI value of 9.3 per cent and underestimated the 42 mm data point by 13 per cent. With the average wear rate from the 38 mm head size ($6.623 \text{ mm}^3/10^6 \text{ cycles}$) used in conjunction with the averages from the other three head sizes, an excellent linear fit was obtained in the 22–38 mm data range (Table 5). This trend underesti-

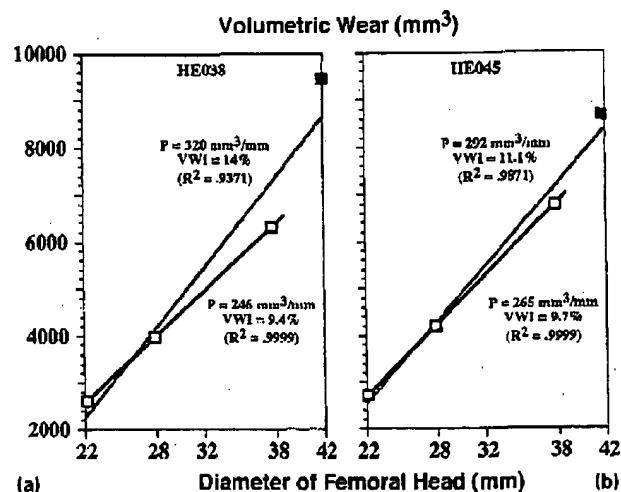


Fig. 7 Comparison of two experiments with four head sizes run in the 12-channel simulator using the Paul load profile. The scatter in wear rates per head size between two experiments run three months apart was less than ± 4 per cent. Linear regression provided an excellent fit in the 22–38 mm range, which undershot the 42 mm point by 13 per cent

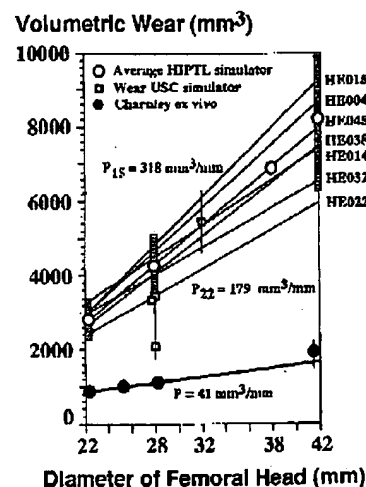


Fig. 8 Summary of linear regression trends calculated for the 22.25–28 mm range in seven PTFE experiments. The average of two 38 mm data points also included from the 12-channel simulator. The location of the average wear rates with ± 2 S.D. (bars) are indicated for the four head sizes used in this study, and for the 28 and 32 mm data reported in the USC study (9). *In vivo* PTFE data presented for comparison (8)

ated the 42 mm data point by 4 per cent (Fig. 8). The overall wear penalty was 240 ± 44 per cent mm^3/mm and the corresponding VWI value was 8.4 per cent/mm (± 43 per cent). Compared to the reported *in vivo* wear rates

(7), the simulator PTFE wear averages were 3.2 to 4.8 times higher (Fig. 8).

In the polyethylene experiment, the wear also increased with increased ball diameter. The average wear rates were 23.2, 31.9 and 32.8 mm³/10⁶ cycles (variation = ± 5.3 per cent) for 22.25, 26 and 28 mm diameters, respectively (Table 4). The wear penalty (gradient *P*) for the linear trends in the 22–28 mm diameter range averaged 1.75 mm³/mm and the VWI value was 7.4 per cent/mm overall. The ratio of PTFE to polyethylene wear rates in the simulator study varied from 117 to 129 times, depending on ball size.

4 DISCUSSION

This serum-based simulator study was designed to provide a broad overview of the wear phenomena associated with two very different polymers, PTFE and polyethylene, in combination with either ceramic or CoCr femoral heads in four sizes. This was also the first study of three femoral head sizes evaluated concurrently in a simulator (with three replicate specimens) and the first report in which any wear experiments were repeated.

The primary observation was that volumetric wear rates increased with respect to ball size in every experiment, for both PTFE and polyethylene cups and with either CoCr or ceramic femoral heads. Therefore, this was the first unequivocal simulator confirmation of Charnley's original observations that cup wear increased uniformly throughout the 22–42 mm range of head size (7). The volumetric wear indices averaged 7.4 per cent/mm and 8.4 per cent/mm for polyethylene and PTFE, respectively. A serum-based wear study in the USC simulator provided volumetric wear indices of 6 per cent when comparing 22.25 and 28 mm heads (15). Clinical reviews of Charnley and Muller hip cases provided volumetric wear indices in the 6–8 per cent/mm range (16) and were therefore comparable to the simulator data in this study. The study from the Mayo Clinic appeared to demonstrate that the lowest polyethylene wear was evidenced by the 28 mm size head (11). It was therefore intriguing that, in all the experiments for this study, there was no instance where the 28 mm head appeared superior to the 22 mm head. Thus, the authors have confirmed Charnley's hypothesis that cup wear was dependent on the size of the femoral head and increased uniformly with diameter at the rate of 6–10 per cent/mm of head size.

A water-based study (17) of stainless steel and zirconia heads also demonstrated that the smaller sizes generally had the least polyethylene wear. The wear of zirconia heads showed a progression with head size from 22 to 32 mm (Fig. 9). Compared to the very low wear rate evident for the 22 mm size (0.3 mm³/10⁶ cycles), the volumetric wear indices were calculated as 650 per cent/mm and 410 per cent/mm for 26 mm and 32 mm

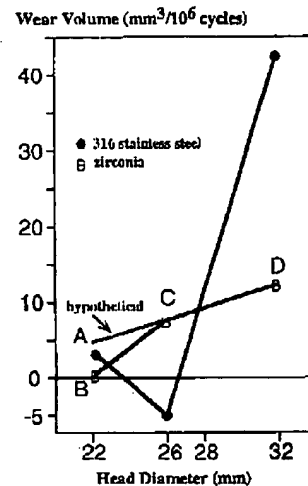


Fig. 9 Volumetric wear rates for polyethylene plotted with respect to size of stainless steel and zirconia heads (17). The almost zero wear value (B) for the 22.25 mm zirconia ball resulted in unrealistically high volumetric wear ratios for 26 and 32 mm heads. To maintain the 10 per cent/mm ratio calculated between C and D would require a wear value (A) of 4.7 mm³/10⁶ cycles (more than 15 times higher than B). The 26 mm metal head also exhibited a large negative volume decrease, thought to be due to errors in the dimensional methods used

sizes, respectively. These were two orders of magnitude larger than the known clinical range of 5–6 per cent/mm (see Table 1). However, comparing the volumetric wear index between 26 and 32 mm sizes, a ratio of 10.1 per cent/mm was obtained. This indicated that the 22 mm zirconia data probably erred on the low side (Fig. 9). Excluding the 26 mm metal head size and comparing the volumetric wear index between 22.25 and 32 mm metal sizes, a ratio of 132 per cent/mm was obtained. This was still an order of magnitude larger than the clinical range.

A subsequent water-based simulator study provided contrary data, that 47 mm CoCr femoral heads created much less polyethylene wear than the 32 mm size. It was thought that this was possibly due to their having a ceramic-like, titanium nitride coating (18). The most recent water-based study of ceramic heads detected zero polyethylene wear and concluded that 'the diameter of the zirconia head, 28 versus 32 mm, seems unimportant' (19). Thus, there were considerable differences between the predictions of these three water-based simulator studies with respect to polyethylene wear and head size.

The PTFE wear magnitudes from this simulator study were comparable to the data from the USC tribology centre (Fig. 8). What was not clear was why both these simulators should produce wear rates three to five times higher in magnitude than Charnley's patient data? The PTFE wear penalty of 240 mm³ increase per millimetre

Table 6 Summary of parameters which could differ remarkably between contemporary simulator studies and Charnley's original study

Number of study	Variation in study parameters
1	Simulator loading parameters too severe
2	1 million simulator load-cycles not equivalent to one year of patient use
3	Contemporary PTFE inferior to Charnley's 'Teflon' cup material
4	Charnley's patients very low performance due to medically challenged status
5	Serum lubrication created high-wear regime

of head size also represented a six-fold increase over the Charnley model (see Table 2). Thus, the accuracy of this study's PTFE wear predictions relative to the Charnley model left much to be desired. There may be five or more possibilities for this discrepancy in wear magnitudes (Table 6).

It is possible that the PTFE test conditions were more severe than seen clinically. However, the polyethylene wear rates run with 22.25 mm heads under identical conditions averaged $23 \text{ mm}^3/10^6$ cycles, which was on the low side compared to clinical results (20–22) of Charnley implants in elderly female and male patients ($30 \text{ mm}^3/\text{year}$; $80 \text{ mm}^3/\text{year}$). Thus the simulator test conditions did not appear to be too severe for polyethylene (10). The same argument applies to whether one million simulator cycles was equivalent to one year of use in the patient. However, one million cycles does in fact represent a reasonable index for patient activity, which can vary by a factor of over 40 times (23).

It is also possible that the PTFE/serum wear interaction was more severe than for PTFE/synovial fluid interactions. Several studies have noted that biological lubricants produced four to eight times higher wear than water (24–26). Therefore, the wear magnitude discrepancy may be partially due to lower activity levels in Charnley's patients and partially due to the choice of serum-based lubrication.

This data set represented over 2900 individual cup weighings, averaging about 320 per experiment. The overall design of the SWM simulator and implant fixtures combined with the weight loss procedures greatly facilitated this degree of data acquisition. These tests also represented a major development period for the SWM 9.9 simulator, extending over a 15 month period. The CoCr experiment HE002 was eliminated, for example, because the wear magnitudes were much lower than all subsequent tests. This being one of the first test runs with the new SWM 9.9 simulator, the most likely reason was error in the machine calibrations. Thus, there were only two valid CoCr wear experiments and these had the highest wear trends (Fig. 7). Possibly the low wear resistance of PTFE was not unduly influenced by secondary effects such as surface characteristics of the

femoral heads. Despite these developments, the overall repeatability in wear rates for three sizes of femoral heads in seven PTFE experiments was within ± 24 per cent ($\pm 2 \text{ S.D.}$, see Table 5). It is likely that this 24 per cent figure can be improved.

The lack of precision in wear data has generally been quite high. Water-based tests in particular have provided considerable variation, with scatter of over ± 70 per cent reported (27). With serum lubrication, the precision of each test (three cups with four to ten wear events) was within ± 6 per cent in this study (± 95 per cent CL). However, the most important aspect of using three cups per experimental set was to detect the break-away behaviour of the wear trend when it occurred. For such break-away behaviour to occur (weight gain), the authors surmised that some wear debris had transferred back on to the cup surfaces instead of being liberated in the usual way. In these experiments, this was a transient effect in only one specimen per set and did not obscure the overall wear trend. This is different from the onset of a high-wear phase which can continue for millions of cycles (28, 29).

The dilemma in such break-away cases was whether to run the linear regression trend for all three cups regardless, delete the break-away specimen from the analysis, or incorporate partial data (from before and after the breakaway points). In this study, any aberrant cup trend was deleted from the analysis as unrepresentative of that set. This demonstrated the need for multi-specimen wear tests run at the same time in the same simulator machine. It is suggested that the minimum acceptable standard should include a wear set of three specimens for each experimental variable (6, 12, 15, 28). Repeated wear assessments are required over a suitable period of time to define the wear trends. Thus the desired number of wear events and hence test duration must be designed with that in mind. Four wear events were used initially in this study as the minimum for the linear regression analysis, but now at least six wear events are preferred (giving seven data points for analysis).

Experience with the pin-on-flat wear screening configuration was gained from 1974 to 1980 at the University of California in Los Angeles (25, 29). Experience with multi-channel hip simulator programs was gained at the Orthopedic Hospital, Los Angeles (5, 12, 15, 30, 31). In terms of clinical accuracy, the simulators predicted on the low side for polyethylene wear and over three times too high for PTFE wear. However, this still compared very favourably with wear screening studies where the clinical accuracy is from 100 to 1000 times lower than *in vivo* wear rates (32). It seems clear in the 1990s that the precision, accuracy and repeatability of wear data from hip simulators will be superior to that from wear screening machines. Comments have been made that it is not possible to assess implant wear by weight loss techniques due to the heavier specimens involved (3, 33). However, with the wear rates in

simulators being much higher than in wear screening devices, the gravimetric techniques of wear assessment are easily applicable, precise and reproducible. It is possible to measure and compensate for polyethylene fluid absorption rates of 8 per cent magnitude relative to wear and have a precision of ± 6 per cent in each wear cup set. Moreover, the clinical relevance of wear rates from hip simulators is far easier to establish (or deny). In the 1990s, the SWM simulator type of concept has proven easy to use and reliable in performance. With the proven advantages of multi-channel test capacity, there will be considerable advancement in the knowledge of how to simulate clinical performance of joint replacement implants.

ACKNOWLEDGMENTS

This study was supported in part by the Howard and Irene Peterson Tribology Foundation, the Department of Orthopedics, Loma Linda University Medical Centre, and KYOCERA Incorporated. The authors are grateful to CERASIV Incorporated and PROTEK Incorporated for their donation of femoral heads. Thanks are due to the computer and machine shop consultants, K. Chinn and R. Moran, and to the support of laboratory personnel, E. Francisco, W. Phipatanakul, S. Johnson and P. Stark.

REFERENCES

- Swanson, A. Limitations of joint simulators. In *Evaluation of Artificial Joints* (Eds D. Dowson and V. Wright) 1977 (Biological Engineering Society, London).
- Duff-Barclay, I. and Spillman, D. T. Total human hip joint prostheses—a laboratory study of friction and wear. *Proc. Instn Mech. Engrs.* 1966, **181**(3), 90–103.
- Wright, K. W. J. and Scales, J. T. The use of hip joint simulators for the evaluation of wear of total hip prostheses. In *Evaluation of Biomaterials* (Eds G. D. Winter, J. L. Leray and K. de Groot), 1980, pp. 135–146 (John Wiley and Sons).
- Nusbaum, H. J., Rose, R. M., Paul, I. L., Crugnola, A. M. and Radin, E. L. Wear mechanisms for ultra-high molecular weight polyethylene in the total hip prosthesis. *J. Appl. Polymer Sci.*, 1979, **23**, 777–789.
- McKellop, H. A. and Clarke, I. C. Evolution and evaluation of materials—screening machines and joint simulators in predicting *in vivo* wear phenomena. In *Functional Behavior of Orthopedic Biomaterials* (Eds P. Ducheyne and G. W. Hastings), 1983, Vol. 2 (CRC Press).
- Clarke, I. C., Fujisawa, A. and Jung, H. Influence of ball diameter on polyethylene wear rates. In *19th Annual Meeting of the Society for Biomaterials*, 1993, p. 57 (Society for Biomaterials).
- Charnley, J., Kamanger, A. and Longfellow. The optimum size of prosthetic heads in relation to the wear of plastic sockets in total replacement of the hip. *Med. Biol. Engng.*, 1969, **7**, 31–39.
- Clarke, I. C., Dai, Q. G., Brahm, A. and Gustafson, G. Effects of serum and water lubrication on PTFE/CoCr implants. In *Trans. 2nd Combined Orthopaedic Research Society of USA, Japan, Canada and Europe*, San Diego, November 1995, p. 204.
- McKellop, H. and Clarke, I. Degradation and wear of ultra-high molecular weight polyethylene. ASTM STP 859, 1985, 351–368 (American Society for Testing and Materials).
- Clarke, I. C. Wear of cups: can we improve on the Charnley? Presented at the 7th Annual Conference on *Techniques and Science for Successful Joint Arthroplasty* (Eds J. P. Collier and M. B. Mayor), Dartmouth Biomedical Engineering Centre, Burlington, Vermont, USA, 1995.
- Livermore, J. and Morrey, B. Effect of femoral head size on wear of the polyethylene acetabular component. *J. Bone Jt Surg.*, 1990, **72A**(4), 518–528.
- McKellop, H., Lu, B. and Benya, P. Friction lubrication and wear of cobalt–chromium, alumina and zirconia hip prostheses compared on a joint simulator. In *Trans. 38th Annual Orthopaedic Research Society*, 1992, p. 402.
- Campbell, P., Ma, S., Yeom, B., McKellop, H., Schmalzried, T. P., and Amstutz, H. C. Isolation of predominantly sub-micron-sized UHMWPE wear particles from periprosthetic tissues. *J. Biomed. Mater. Res.*, 1995, **29**, 127–131.
- Anissian, L., Yu, L., Ching, B. and Frykman, E. Qualitative analysis of the wear debris recovered from a hip joint simulator. To be presented at the 5th Annual Biomaterial Congress, Ontario, Canada, May 1996.
- McKellop, H., Ebrahmdadeh, F., Lu, B. and Sarmiento, A. Effect of ball material, diameter and surface roughness on the wear of polyethylene acetabular cups. In *21st Annual Meeting of the Society for Biomaterials*, 1995 (Society for Biomaterials).
- Clarke, I. C., Gustafson, A., Jung, H. and Fujisawa, A. Hip simulator ranking of polyethylene wear: Comparison between ceramic heads of different size. *Acta Orthop. Scand.* (to be published).
- Derbyshire, B., Fisher, J., Dowson, D., Hardaker, C. and Brummitt, K. Comparative study of the wear of UHMWPE with zirconia ceramic and stainless steel femoral heads in artificial hip joints. *Med. Engng Physics*, 1994, **16**, 229–236.
- Pappas, M. J., Makris, G. and Buechel, F. F. Titanium nitride ceramic film against polyethylene. *Clin. Orthop. Rel. Res.*, 1995, **317**, 64–70.
- Saikko, V. Wear of the polyethylene acetabular cup. The effect of head material, head diameter and cup thickness studied with a hip simulator. *Acta Orthop. Scand.*, **66**(6), 501–506.
- Charnley, J. and Halley, D. K. Rate of wear in total hip replacement. *Clin. Orthop.*, 1975, **112**, 170–179.
- McCoy, T. H., Salvati, E. A., Ranawat, C. S. and Wilson Jr., P. D. A fifteen-year follow-up study of one hundred Charnley low-friction arthroplasties. *Orthop. Clin. N. Am.* 1988, **19**(3), 467–476.
- Clarke, I. C. Role of ceramic implants. *Clin. Orthop. Rel. Res.*, 1992, **282**, 19–30.
- Schmalzried, T. P. Factors correlating survival of metal/metal bearings. In *Proc. Metal/Metal Hip Prostheses Past Performance and Future Directions* (Eds H. C. Amstutz and T. P. Schmalzried) 1995 (Joint Replacement Institute Orthopaedic Hospital, Los Angeles).

- 24 Charnley, J. Wear of plastics materials in the hip joint. In *Plastics in Medicine and Surgery*, 1975, pp. 3.1-3.10 (Plastics and Rubber Institute).
- 25 McKellop, H., Clarke, I. C., Markold, K. and Amstutz, H. C. Wear characteristics of UHMW polyethylene: A method for accurately measuring extremely low wear rates. *J. Biomed. Mater. Res.*, 1978, **12**, 895-927.
- 26 Kumar, P., Oka, M., Ikeuchi, K., Shimizu, K., Yamamuro, T., Okumura, H. and Kotoura, Y. Low wear rate of UHMWPE against zirconia ceramic (Y-PSZ) in comparison to alumina ceramic and SUS 316L alloy. *J. Biomed. Mater. Res.* 1991, **25**, 813-828.
- 27 Saikko, V. Wear of polyethylene acetabular cups against alumina femoral heads. Five prostheses compared in a hip simulator for 35 million walking cycles. *Acta Orthop. Scand.*, 1993, **64**(5), 507-512.
- 28 Saikko, V. Wear of polyethylene acetabular cups against zirconia femoral heads studied with a hip joint simulator. *Wear*, 1994, **176**, 207-212.
- 29 McKellop, H., Clarke, I. C., Markold, K. and Amstutz, H. Friction and wear properties of polymer, metal and ceramic prosthetic joint materials evaluated on a multi-channel screening device. *J. Biomed. Mater. Res.*, 1981, **15**, 619-653.
- 30 Clarke, I. C., Starkebaum, W., Hossainian, A., McGuire, P., Okuda, R., Salovey, R. and Young, R. Fluid-sorption phenomena in sterilized polyethylene acetabular prostheses. *Biomaterials*, 1985, **3**(6), 184-188.
- 31 Clarke, I. C. Wear of artificial joint materials. IV: Hip joint simulator studies. *J. Engng Medicine*, 1981, **10**, 189-198.
- 32 Clarke, I. C. and Gustafson, A. Wear simulator data for ceramic/PE: Is there valid data to support clinical usage in USA? In *6th Biomaterial Symposium on Implant Materials in Orthopaedic Surgery* (Eds H. Willert and G. Buchhorn), 1996 (Gottingen University, Germany).
- 33 Dowson, D., Jobbins, B. and Seyed-Harraf, A. An evaluation of the penetration of ceramic femoral heads into polyethylene acetabular cups. *Wear*, 1993, **162-164**, 880-889.

WISCONSIN

Information Retrieval
For Business and Industry

TECHSEARCH

WTS Number: 333110



Request Date: 2/09/05 11:55 AM

Conf Number: 108825

Requester: Heather Rories
Heller Ehrman
1666 K Street, NW
Suite 300
Washington, DC 20006

RUSH

Company Phone:

Delivery: Email

Requester Phone: 202-912-2177

Instructions:

Fax: 202-912-2020

Requester Email: hrories@hewm.com

Send-To Email: hrories@hewm.com

RUSH

Reference: 37697-0039chowdhury

Refer Off Campus

Clarke et al., Proc Inst Mech Eng [H]. 1997;211(1):25-36.

ENG
SING M464
P2801

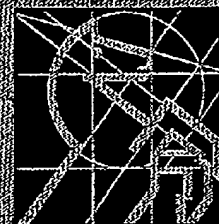
An outreach service of the Kurt F. Wendt Library, University of Wisconsin - Madison
Email: wts@engr.wisc.edu | Web: <http://www.wisc.edu/techsearch> | Phone: (608) 262-5917

Copyright Royalty: \$

Of Pages: 12

0954-4/19

PROCEEDINGS OF THE
**Institution of
Mechanical
Engineers**



IMECH E

1847

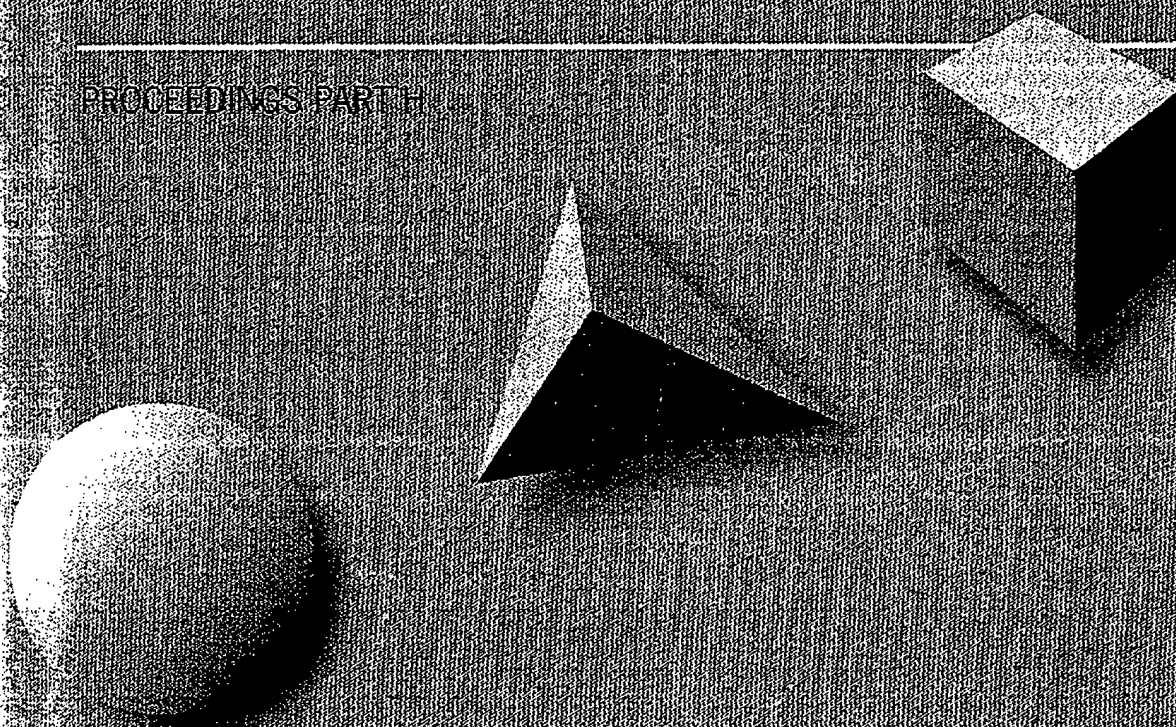
FOUNDATION

N6
1464
2801

JOURNAL OF

Engineering in Medicine

PROCEEDINGS PART H



1997 Vol 211 No H1
ISSN 0954-4119

Factors contributing to the wear of polyethylene in clinical practice I D Learmonth and J L Cunningham	49
The pathogenesis of osteolysis in two different cementless hip replacements I D Learmonth, E J Smith and J L Cunningham	59
The role of polyethylene wear in joint replacement failure M A McGee, D W Howie, S D Neale, D R Haynes and M J Pearcy	65
Clinical wear behaviour of ultra-high molecular weight polyethylene cups paired with metal and ceramic ball heads in comparison to metal-on-metal pairings of hip joint replacements M Semlitsch and H G Willert	73
Kinematics of the MATCO [®] hip simulator and issues related to wear testing of metal-metal implants J B Medley, J J Krygier, J D Bobyn, F W Chan, A Lippincott and M Tanzer	89
Frictional heating of bearing materials tested in a hip joint wear simulator Z Lu and H McKellop	101
Wear of the high-density polyethylene socket in total hip arthroplasty and its role in endosteal cavitation B M Wroblewski	109
Development of standards for orthopaedic implants J P Paul	119
Keywords	127

Proceedings of the Institution of Mechanical Engineers

The Proceedings is the premier publication of the Institution of Mechanical Engineers. The Proceedings is published in ten parts:

- Part A Journal of Power and Energy
- Part B Journal of Engineering Manufacture
- Part C Journal of Mechanical Engineering Science
- Part D Journal of Automobile Engineering
- Part E Journal of Process Mechanical Engineering
- Part F Journal of Rail and Rapid Transit
- Part G Journal of Aerospace Engineering
- Part H Journal of Engineering in Medicine

- Part I Journal of Systems and Control Engineering
- Part J Journal of Engineering Tribology

Each Part of the Proceedings has an eminent engineer as Editor who is assisted by an Editorial Board. Papers published in the Proceedings must attain a high standard, and all papers, other than invited lectures and addresses, are refereed. Papers are invited for consideration for publication from both members of the Institution and non-members; from United Kingdom authors and overseas authors. Authors should read the notes on the inside back cover for information regarding submission.

Subscription information

Journal of Engineering in Medicine Proceedings Part II
The Americas US\$471; Rest of World £269

Combined price, Parts A-J
The Americas US\$3483; Rest of World £1990

All prices include postage and packing. Copies sent outside the UK benefit from air-speeded despatch to ensure fast delivery.

All current subscription inquiries to: Sales Department, Mechanical Engineering Publications Limited, Northgate Avenue, Bury St Edmunds, Suffolk IP32 6BW, England (Tel: 01284 763277 Telex: 817376 Fax: 01284 704006)

Back issues may be obtained from: Wm Dawson and Sons Limited, Back Issues Department, Cannon House, Folkestone, Kent CT19 5EE, England (Tel: 01303 850101)

© The Institution of Mechanical Engineers 1997

This publication is copyright under the Berne Convention and the International Copyright Convention. All rights reserved. Apart from any fair dealing for the purpose of private study, research, criticism or review, as permitted under the Copyright, Designs and Patents Act, 1988, no part of this publication may be reproduced, stored in a retrieval system or transmitted in any form or by any means without the prior permission of the copyright owners. Reprographic reproduction is permitted only in accordance with the terms of licences issued by the Copyright Licensing Agency, 90 Tottenham Court Road, London W1P 9ITE. *Unlicensed multiple copying of the contents of the publication without permission is illegal.* Inquiries should be addressed to: The Managing Editor, Mechanical Engineering Publications Limited.

The publishers are not responsible for any statement made in this publication. Data, discussion and conclusions developed by authors are for information only and are not intended for use without independent substantiating investigation on the part of potential users. Opinions expressed are those of the authors (or contributors to discussion) and are not necessarily those of the Institution of Mechanical Engineers or its publishers.

Typeset and printed in Great Britain by The Charlesworth Group, Huddersfield

Prohibitive Failure Rate of the Total Articular Replacement Arthroplasty at Five to Ten Years

Robert J. Treuting, MD, Douglas Waldman, MD, James Hooten, MD,
Thomas P. Schmalzried, MD, and Robert L. Barrack, MD

ABSTRACT

Five- to 10-year follow-up was obtained on a series of total articular replacement arthroplasties performed at a single university-affiliated teaching hospital. Eighty arthroplasties were performed on 64 patients. Twelve patients (accounting for 14 hip arthroplasties) died. Follow-up was obtained on 62 of the 66 remaining hips (94%). Thirty-five hips had been revised (56%), 32 for acetabular loosening and 3 for femoral loosening, 1 of which led to femoral stem fracture. The average time to revision was 72 months (22 to 132 months). The revision procedures were extensive in terms of operative time, blood loss, and necessity of acetabular bone grafting. Follow-up of the 27 that had not been revised averaged 84 months and revealed 1 hip excellent, 5 good, 1 fair, and 20 poor results. The overall clinical failure rate (revisions plus clinically poor results) was 89% (55/62 hips). These results are far inferior to conventional total hip replacement, and the extent of the revision procedures indicates that this is not a conservative alternative to conventional total hip replacement.

Total articular replacement arthroplasty (TARA) as described by Townley¹ includes a metallic hemispheric cup attached to a curved thin stem and a thin polyethylene acetabular component that may be metal backed. Polymethylmethacrylate has usually been used for fixation, although components may be press fit. Resurfacing arthroplasty was originally proposed as a conservative alternative in response to the initially reported poor results with cemented conventional total hip arthroplasty in younger, active patients.² The objectives of TARA were to preserve bone stock by resecting only the

diseased portion of the head; to maintain the normal anatomy and mechanics of the hip joint; and to approximate in vivo transmission of stress to the supporting femoral bone.³

Early clinical results were promising^{1,2} although later reports indicated that failure rates increased with longer follow-up. Follow-up beyond 5 years has rarely been reported. The purpose of this report is to present a long-term clinical and radiographic analysis of the TARA performed at one university teaching hospital.

MATERIALS AND METHODS

Total articular replacement arthroplasty with the TARA device was performed on 80 hips in 64 patients from 1982 to 1989 at the Veterans Administration Medical Center in Alexandria, Louisiana, which is a Tulane University-affiliated teaching hospital. All cases were performed or supervised by a senior hip surgeon with interest and training in this procedure. Four patients (4 hips) have been lost to follow-up, leaving 76 hips in 60 patients available for study in this series. Fifty-seven patients were male, and 3 patients were female. Procedures were performed on 40 right hips and 36 left hips. Sixteen patients had bilateral procedures that were staged at least 6 months apart. Preoperative diagnoses included osteoarthritis (35 hips), avascular necrosis (24 hips), rheumatoid arthritis (10 hips), and posttraumatic arthritis (7 hips). The average age at time of operation was 61.7 years (range, 38 to 76). Acetabular component sizes ranged from 56 mm to 62 mm in outer diameter, while femoral component sizes ranged from 45 mm to 55 mm in head diameter. Components were cemented in 72 of 76 procedures. All procedures were performed with the patient in the lateral position through an anterolateral approach without trochanteric osteotomy.

Clinical evaluation consisted of a modified Harris hip score in those patients who retained their original TARA device, as well as from those patients who have had revisions or resections of their original TARA.

Dr. Treuting is Resident, Dr. Waldman is Assistant Clinical Professor, Dr. Hooten is Resident, and Dr. Barrack is Professor and Director of Adult Reconstructive Surgery, Department of Orthopaedic Surgery, Tulane University School of Medicine, New Orleans, Louisiana.

Dr. Schmalzried is Assistant Professor, Department of Orthopaedic Surgery, Harbor-UCLA Medical Center, Torrance, and Associate Medical Director, Joint Replacement Institute, Los Angeles, California.

Radiographs were reviewed for lucent lines, lysis, and component migration. In patients who had revision surgery, the radiograph prior to revision was evaluated. Components that had definite evidence of migration or a continuous 100% radiolucent zone were classified as radiographically loose.

Operative data obtained on revisions include length of surgery, blood loss, extent of bone loss and necessity of bone grafting.

RESULTS

Twelve patients (14 hips) had died prior to this study; no revisions had been performed in these hips. Of the remaining 66 hips (52 patients), clinical follow-up was obtained on 62 (94%). Revision or resection arthroplasty had been performed in 35 of these 62 hips (56%). The average time to revision was 72 months (range, 22 to 126).

The average follow-up of the 27 unrevised TARA hips was 84.4 months (range, 45 to 126). The average Harris hip score of patients who retained the TARA implant was 55.9 (range, 18 to 93) with excellent, 5 good, 1 fair, and 20 poor results. The overall clinical failure rate (revisions and clinically poor results) was 89% (55/62 hips).

Radiographic analysis of unrevised hips revealed a 22% incidence of acetabular loosening, 16% acetabular lysis, 22% femoral loosening, and 9% femoral lysis. Twelve of these hips showed definite component loosening for an overall anticipated failure rate (revision plus radiographic failures) of 76% (47/62).

The cause of failure leading to revision was identified by review of prerevision radiographs. There were three cases of femoral loosening. One case with femoral loosening was associated with fracture of the stem (Figure 1). This fracture likely resulted from loosening of the hemispheric portion with subsequent excessive transfer of load to the well-fixed stem. In the remaining 27 cases, acetabular loosening was the primary mechanism of failure. Cases were evenly distributed between failure of the bone-cement interface (Figure 2) and the socket-cement interface (Figure 3). In 9 of these cases the femoral component was also noted to be loose at the time of revision (Figure 4).

In analyzing the radiographs of the 20 patients who were considered clinical failures (hip score <70), 2 showed evidence of socket-cement interface failure of the acetabular component. Bone cement failure of the acetabular component was evident in 4 cases; while an additional 3 showed evidence of femoral loosening. One case showed evidence of impending failure of both components. In the remainder of cases, incomplete radiolucent lines were noted.

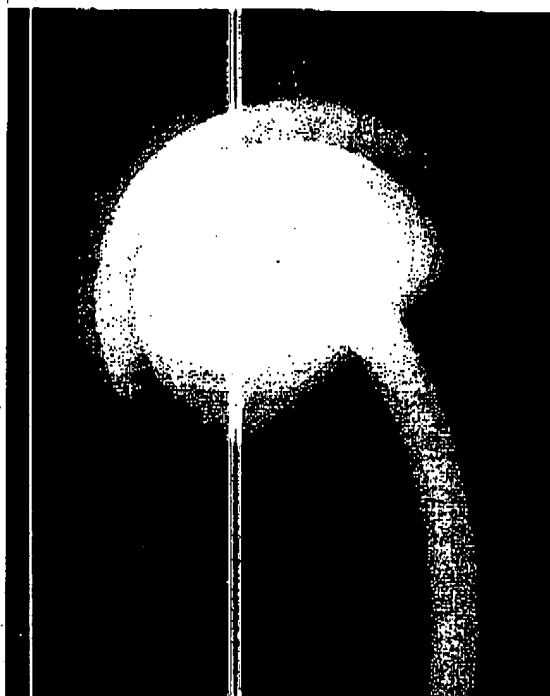


Figure 1. Seven-year follow-up radiograph of 58-year-old man who underwent total articular replacement arthroplasty for avascular necrosis. Shell was grossly loose at surgery.

Four hips in this series had noncemented acetabular components; none had been revised, and all 4 were radiographically stable at follow-up, with no evidence of component migration or complete or excluding radiolucent line. Two of these patients were doing well clinically and 2 were doing poorly according to their hip scores, but both were Charnley class C patients with medical problems that limited their ambulation.

Clinical and operative data were also obtained on 25 of 35 hips that had undergone revision surgery. The average follow-up was 28 months (range, 12 to 64), and the average Harris hip score was 67 (range, 44 to 89). Procedures performed included 3 resection arthroplasties, 17 conventional total hip arthroplasties, 3 bipolar arthroplasties, and 2 revisions of the TARA acetabular component. The average operative time for these procedures was 3 hours, 45 minutes (range, 2 to 6 hours); average blood loss was 1275 cc (range, 650 to 2000); and structural bone graft was used in 30% of these acetabular reconstructions because of extensive bone loss. The resection arthroplasties were performed because of extensive acetabular bone loss (Figure 5).

DISCUSSION

Townley¹ reported on 222 TARAs with an average follow-up of 20 months and stated that the

PROHIBITIVE LONG-TERM FAILURE RATE OF THE TARA

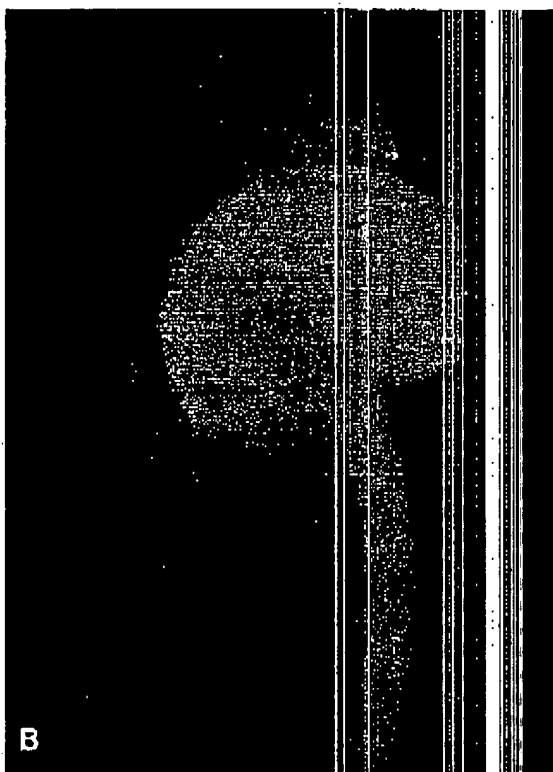
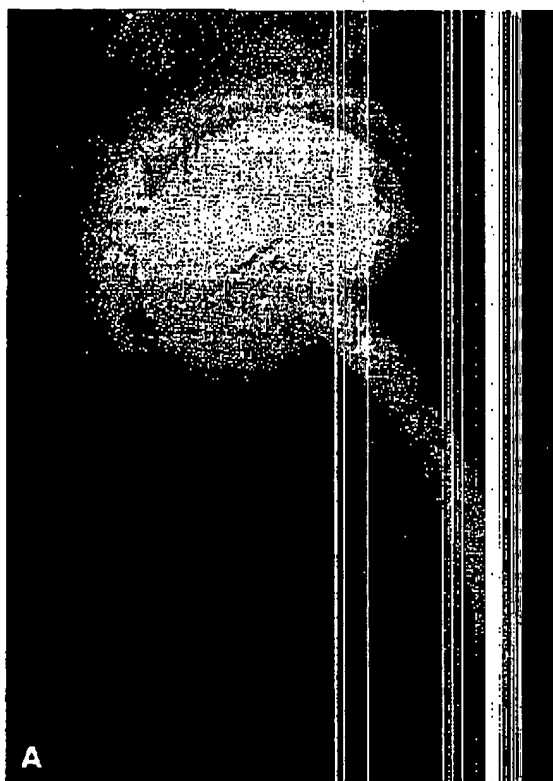


Figure 2. (A) Postoperative radiograph immediately after total articular replacement arthroplasty in a 65-year-old male. (B) at 8-year follow-up, there is loosening and migration of both components with acetabular bone loss.

overall clinical results were similar to those reported for conventional hip replacement. Six failures were attributed to acetabular loosening that was felt to be associated with faulty positioning at the time of implantation. Mallory and colleagues³ reported 24-month follow-up on 64 hips with greater than 90% excellent results with regard to pain and function and an overall failure rate of 6%. Mallory and colleagues³ did report a high incidence of acetabular radiolucencies, as well as sclerosis and position change about the femoral stem, which were likely indicative of future clinical failures. Cohn and colleagues² reported results on 29 hips at an average follow-up of 5 years. They reported only 2 failures (7%) out of 29 hips with an average Harris hip score of 90 at follow-up. They reported no stem position changes. Radiolucencies about the acetabulum greater than 1 mm, however, were seen in over half the hips at follow-up.

Head⁴ reported clinical and radiographic results on 67 hips with an average follow-up of 3.3 years. At the time of the study, Head reported a definite failure rate of 1.9% and a 22.9% anticipated failure rate based on radiographic evidence of impending failure. Factors attributed by Head to



Figure 3. Follow-up radiograph after total articular replacement arthroplasty. At 7 years, complete failure at the socket-cement interface is apparent.

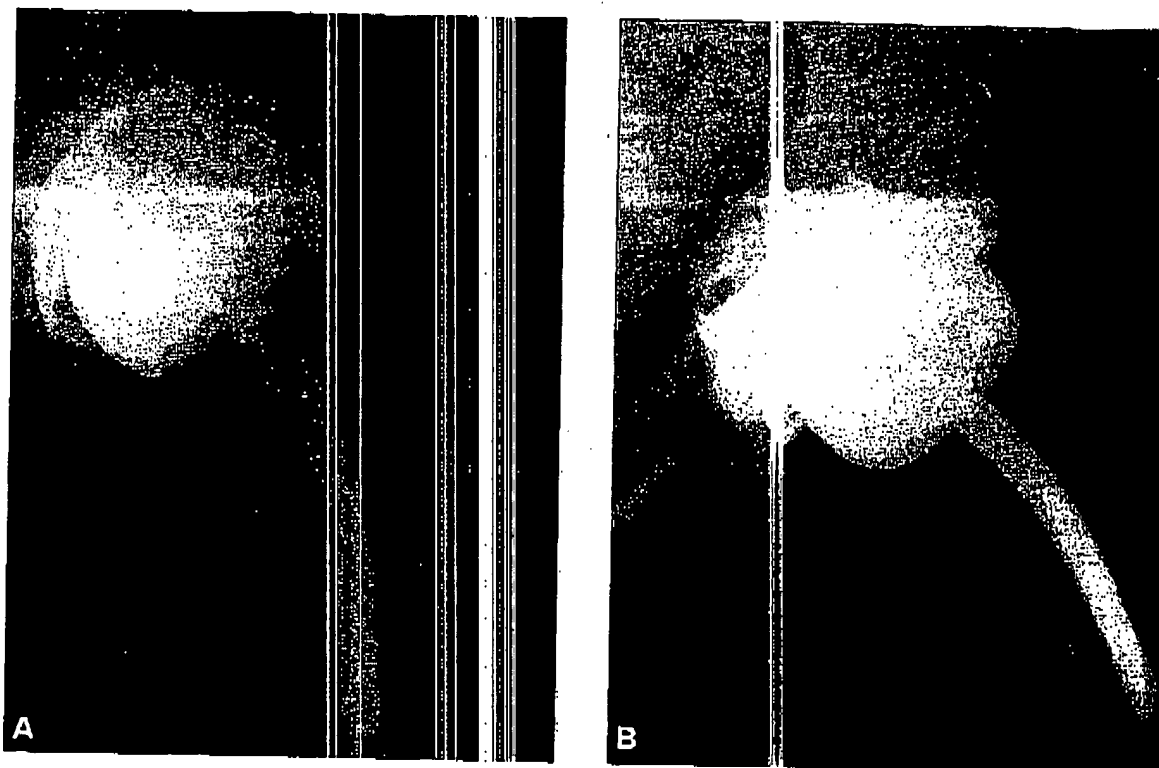


Figure 4. (A) Postoperative radiograph immediately after total articular replacement arthroplasty in a 61-year-old man; (B) at 9 years, gross migration of the femoral stem and acetabular lysis is evident.

the high incidence of failure included young patient age and high activity levels, as well as poor cement distribution on the acetabular side with subsequent micromotion from increased frictional torque with the large-diameter TARA prosthesis.

Previous studies have reported results at follow-up intervals of 5 years or less. To our knowledge, this series represents the longest reported follow-up of the TARA. The results of our study confirm Head's conclusion that long-term results of TARAs are not promising.⁴ Despite an average patient age of almost 62 years and a relatively sedentary group of patients, 85% of the hips in this series were failures.

Like the experience with other hip resurfacing arthroplasty systems,⁵⁻⁸ acetabular bone loss and component loosening constituted the most common types of failure in this series. Several features of the TARA may be suboptimal, including the large diameter of the bearing, the thin polyethylene, and the metal backing.⁹⁻¹² Individually, these factors are associated with increased polyethylene wear and they are undoubtedly worse in combination. The volumetric wear rate of hip resurfacing components is 4 to 10 times higher than that of a conventional 28-mm hip bearing.⁹ Polyethylene wear particles play a central role in acetabular bone loss and component loosening.^{8,13} The increased rate of poly-

ethylene wear is undoubtedly a contributing factor to the accelerated failure rate of these TARAs.

Resurfacing arthroplasty was originally proposed as a conservative alternative to cemented total hip arthroplasty in young active patients. One of the main objectives of the TARA and resurfacing arthroplasty in general was to preserve bone stock, thereby enhancing the potential for revision in the event of failure.¹ While this objective may have been met on the femoral side, the large acetabular components necessitate sacrifice of acetabular bone stock. Additional acetabular bone stock was subsequently lost as a result of lysis and loosening.

A discouraging result of this study was the complexity and outcome of revisions of TARA devices. Our data indicate that TARA revisions are at least as difficult as conventional total hip arthroplasty revisions. We noted long operative times and substantial blood loss. Thirty percent of our patients had structural grafting for acetabular bone loss. These revision hips had an average Harris hip score of 67. We conclude that total articular replacement arthroplasty is not conservative and is a poor alternative to conventional total hip arthroplasty.

REFERENCES

1. Townley CO. Hemiarthroplasty and total articular replacement arthroplasty of the hip with the fixed femoral cup. *Orthop Clin North Am.* 1982;13(4):869-893.

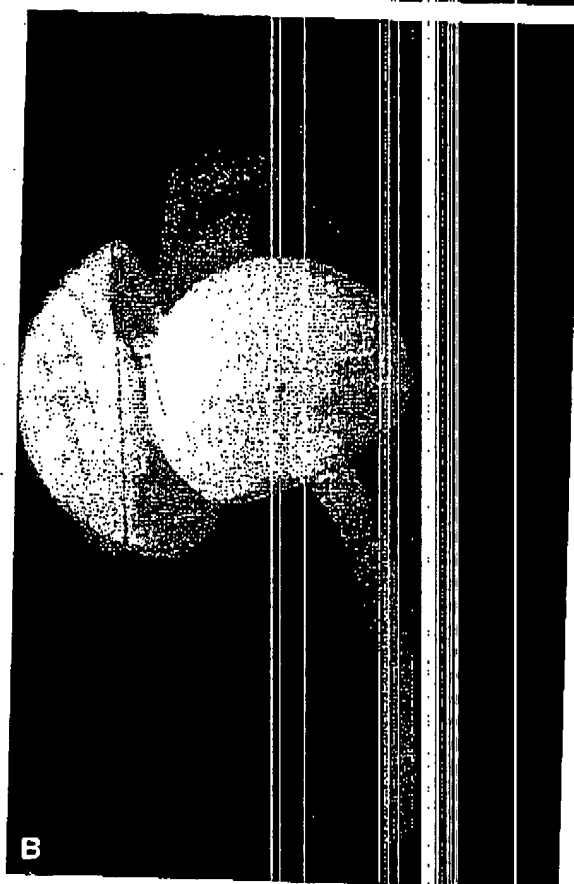


Figure 5 (A) Postoperative radiograph immediately after total articular replacement arthroplasty; (B) at 8-year follow-up, acetabular component has broken into the pelvis; (C) resection arthroplasty was elected because of extensive bone loss.

2. Cohn JT, Froimson AI, Brahas MA, Greenwald AS. Total articular replacement arthroplasty. *Orthopedics*. 1988;114:551-558.
3. Mallory TH, Ballas S, Vanotia G. Total articular replacement arthroplasty: a clinical review. *Clin Orthop*. 1984;185:131-136.
4. Head VC. Total articular resurfacing arthroplasty: analysis of failure in sixty-seven hips. *J Bone Jt Surg*. 1984;66A(1):28-34.
5. Schmalzried TP, Guttman D, Grcula M, Amstutz HC. The relationship between the design, position, and articular wear of acetabular components inserted without cement in the development of pelvic osteolysis. *J Bone Jt Surg*. 1994;76A:677-688.
6. Amstutz HC, Graf-Rodford A, Mai LL, Thomas BJ. Surface replacement of the hip with the Tharies System: two to five-year results. *J Bone Jt Surg*. 1981;63A:1069-1077.
7. Jolley MJ, Salvati EA, Brown GC. Early results and complications of surface replacement of the hip. *J Bone Jt Surg*. 1982;64A:366-377.
8. Schmalzried TP, Jasty M, Harris WH. Periprosthetic bone loss in total hip arthroplasty: the role of polyethylene wear debris and the concept of the effective joint space. *J Bone Jt Surg*. 1992;74A:849-863.
9. Kabo JM, Gebhard JS, Loren C, Amstutz HC. In vivo wear of polyethylene acetabular components. *J Bone Jt Surg*. 1993;75B:254-258.
10. Mai MT, Schmalzried TP, Dorey FJ, et al. Effect of bearing surface size on the longevity of cemented hip arthroplasty: frictional torque or wear debris? *Orthop Trans*. 1993;17:790. Abstract.
11. Bartel D, Bicknell VL, Wright TM. The effect of conformity, thickness, and material on stresses in ultra-high molecular weight components for total joint replacement. *J Bone Jt Surg*. 1986;68A:1041-1051.
12. Cates HL, Faris PM, Keating EM, Ritter MA. Polyethylene wear in cemented metal-backed acetabular cups. *J Bone Jt Surg*. 1993;75B:249-253.
13. Schmalzried TP, Kwong LM, Jasty M, et al. The mechanism of loosening of cemented acetabular components in total hip arthroplasty: analysis of specimens retrieved at autopsy. *Clin Orthop*. 1992;274:60-71.

John Charnley

*Low Friction
Arthroplasty of the Hip*

Theory and Practice

With 440 Figures, 205 in Colour

Springer-Verlag Berlin Heidelberg New York 1979

Chapter 1

Low Friction Principle

The term low friction arthroplasty (or more correctly low frictional torque arthroplasty) was coined to emphasize the small diameter of the prosthetic head (22 mm) essential to the underlying theory. Low friction arthroplasty (LFA) is characterised even more particularly by the combination of a small prosthetic femoral head with a socket of maximum external diameter. Consequently the socket has maximum wall thickness.

The theory of low frictional torque arthroplasty is summarized in Fig. 1.1 reproduced from the Lancet 1961 under the title 'Arthroplasty of the hip—a new operation'.⁽¹⁾

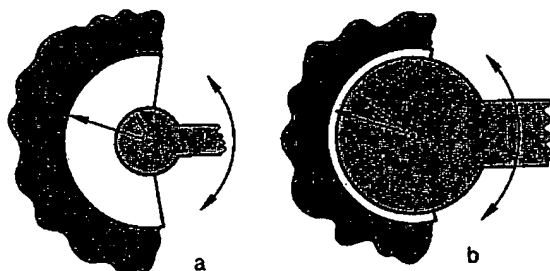


Fig. 1.1a, b. Original illustration of the low friction torque principle applied to hip arthroplasty. a Thick socket—small femoral head: difference in radii favours socket remaining stationary; b not so with only slight difference in radii

Lubrication of Animal and Artificial Joints

The author's approach to total hip replacement from the point of view of lubrication started as a result of a chance encounter with a patient who had a Judet femoral head replacement for osteoarthritis 1 or 2 years previously and whose hip in certain positions emitted an audible squeak. Enquiries established that colleagues had also had similar experiences. In the X-rays the stem of the

prosthesis was seen to be lying in a grossly enlarged track in the femur, and this suggested that under load high friction between the head and the arthrotic socket was resisting movement and that the movement was now taking place between the loose stem and the femur.

This incident served to emphasize the ignorance of basic principles of lubrication, as applied to artificial animal joints, which existed at that time. The mere fact that a polished sphere of a plastics material, or of metal, felt 'slippery' when wetted with tissue fluids and handled in surgical rubber gloves, was no proof that this slippery behaviour would persist in an arthrotic acetabulum under heavy loads.

Lubrication of Animal Joints

At that time the universally accepted theory of lubrication in animal joints gave a dominant role to the action of synovial fluid. Maconnail (1950)⁽²⁾ was impressed by the incongruity existing between joint surfaces in the range of movement used when moving under load, compared with what he called the 'close-packed' situation adopted by some joints, as part of a muscle-sparing mechanism, when 'standing at ease'. Maconnail saw in the incongruity of joint surfaces Nature adopting the principle of hydrodynamic lubrication, demonstrated par excellence in the Michel bearing, where convergent wedges of fluid generate pressure under the action of rotation and separate the surfaces moving under load.

Applied to animal joints however this concept was not convincing, because slow motion, and especially slow oscillating motion, is not ideally suited to the persistence of full-thickness fluid films between sliding surfaces.

4 — Low Friction Principle

Up to that time the only experimental work which had been published on the lubrication of animal joints was that of E. Shirley Jones (1936)⁽³⁾, and of a number of experiments the one of greatest interest was that in which he made a freshly amputated human finger joint function as the pivot of a pendulum. This was an elegant experiment because it explored the resistance to movement of a loaded joint with the surfaces sliding at different speeds. This is because of the well-known fact of a pendulum that the time for each swing is the same whether the amplitude be large or small; therefore at the start of the experiment the speed of sliding will be high when the amplitude is great and will get progressively less as the amplitude decays. In his experiments with the amputated finger joint Jones found that when plotted against

time the decrement of each swing behaved in an exponential fashion, which meant that frictional resistance was disproportionately high at high speeds of sliding. This was consistent with the viscous behaviour of a fluid and from this it was concluded that lubrication of the finger joint must incorporate a hydrodynamic mechanism (Fig. 1.2).

The regime of lubrication which is the diametric opposite of hydrodynamic lubrication is known as 'boundary' lubrication. This mode of lubrication is equivalent to the sliding of dry surfaces which possess intrinsically slippery qualities; the extreme examples being graphite or molybdenum sulphide or polytetrafluorethylene. Also in this category is the lubricating action of substances which react chemically with the sliding surfaces and thereafter function as molecular films too thin to show viscosity in accordance with the laws of fluid mechanics. A good example of this is the lubricating action of fatty acids such as the oleic, stearic, palmitic acids, etc., which form soaps in combination with the metal surfaces of plain bearings. The intriguing feature of this mode of lubrication is that though extremely thin, as a result of being bound chemically to the sliding surfaces, the lubricating films are more resistant to rupture than thick films of grease or oil unable to make a chemical bond with the sliding surfaces. In these latter cases a film of oil or grease would be able to remain intact only as a result of the (relatively small) molecular forces acting between the molecules of the oil itself.

The boundary mode of lubrication seemed to the author ideally suited to the lubrication of slow-moving, heavily loaded animal joints and especially since these were exposed to oscillating motion and capable of remaining stationary under load for several seconds without exhibiting 'stiction' at the moment of resuming movement. It seemed possible that Jones had made an error in choosing a finger joint for the pivot of his pendulum because a finger joint is unstable in the absence of the collateral ligaments and to retain the ligaments would offer greater resistance at large amplitudes of swing than at small ones; this could explain an exponential pattern of decay of amplitude without postulating a viscous fluid mechanism.

The author repeated the pendulum experiment, this time choosing a human ankle joint (Fig. 1.3).

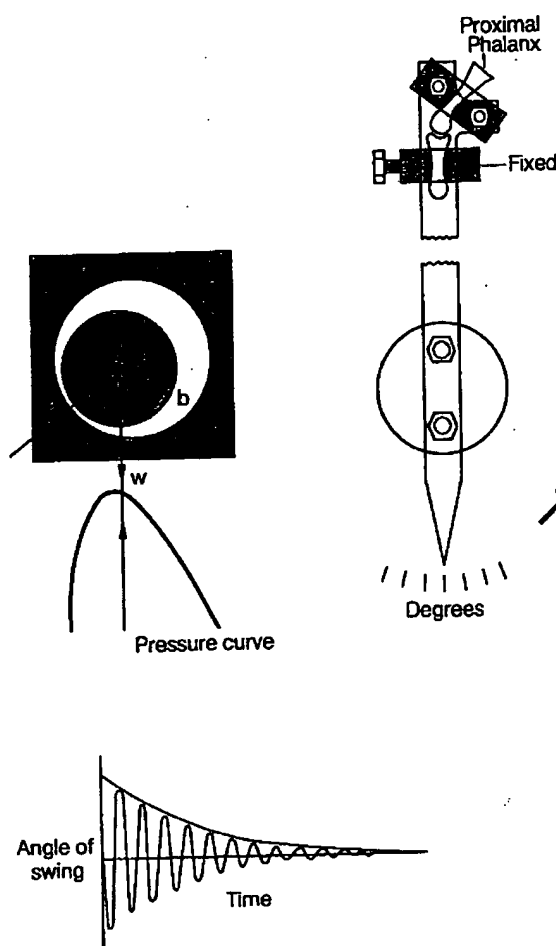


Fig. 1.2. Original experiment of E. Shirley Jones reproduced from his paper

ed in an
frictional
at high
the vis-
was con-
int must
Fig. 1.2).
diametric
known
lubrica-
surfaces
ties; the
bdenum
this cat-
es which
es and
thin to
of fluid
ubricat-
stearic,
ombina-
gs. The
ation is
f being
e lubri-
re than
a chem-
e latter
ble to
latively
mole-

ned to
f slow-
l espe-
g mo-
under
g 'stic-
ent. It
ror in
endu-
bsence
e liga-
ampli-
ld ex-
litude
sm.
ment,
. 1.3).

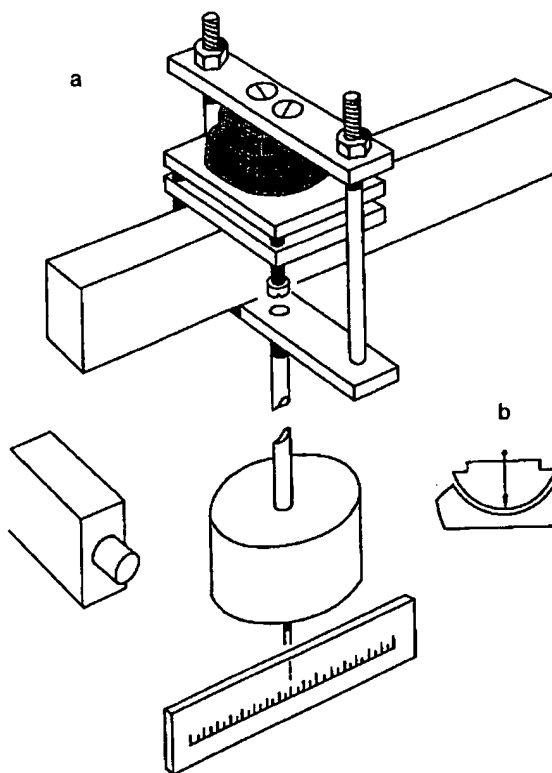


Fig. 1.3. Pendulum experiment using human ankle-joint

Because of the deep curvature of the components of the ankle joint this biological pivot was self-locating in the absence of collateral ligaments. In these experiments the decay of amplitude followed a straight line (Fig. 1.4) indicating that the coefficient of friction in the joint remained the same despite changes in the rate of sliding. This is a recognised feature of boundary friction within certain fairly wide limits of speed. It was interesting also to note that the straight-line behaviour of the decrement of amplitude was not greatly changed whether the ankle joint was visibly wetted with synovial fluid or had been wiped clean of visible liquid with a dry cloth. This suggested that a smear of lubricant was as effective as a large volume, a state of affairs more in accordance with the theory of boundary lubrication than hydrodynamic lubrication.

Against the theory of boundary lubrication as the sole explanation of lubrication in animal joints is often advanced the fact that the coefficient of friction of an animal joint is so astonishingly low

Lubrication of Animal and Artificial Joints — 5

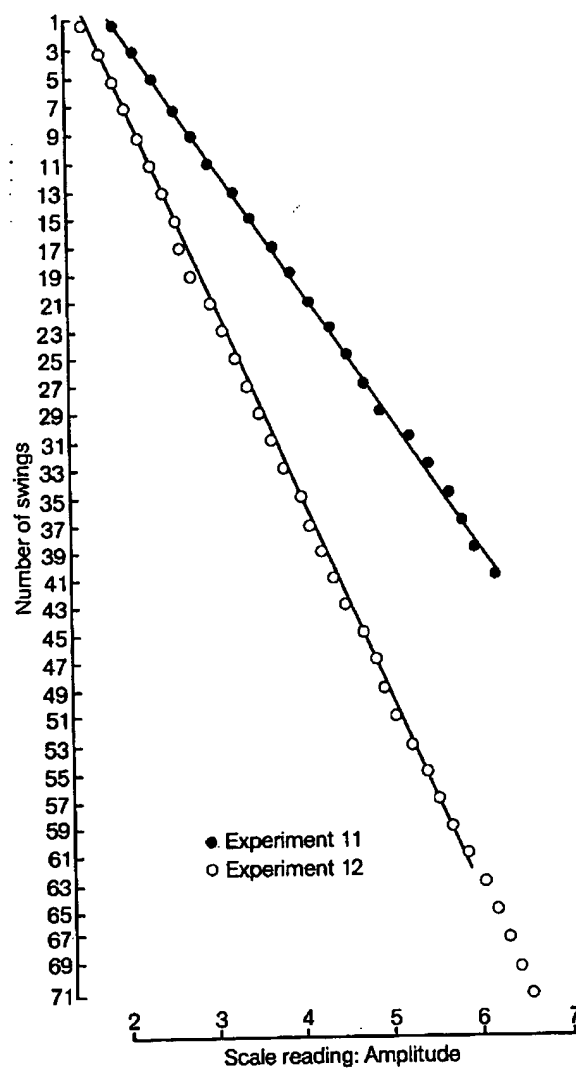


Fig. 1.4. Graphs of decay of amplitude with number of swings. Increase in number of swings when visible synovial fluid was not wiped away with dry cloth (Expt. 12 compared with Expt. 11) did not change straight line performance

(in the region of 0.01 or even less) and in ordinary engineering practice most examples of boundary lubrication have coefficients of friction in the region of 0.10 or higher.

However, it is still possible that the last word has not yet been said on the ultimate nature of lubrication in animal joints and, as is commonly the case in matters of lubrication, a mixed regime of fluid film and boundary lubrication probably exists, with Nature having discovered a unique means of making a mixed regime.

6 — Low Friction Principle

Synovial Fluid as a Lubricant

In the designing of a total joint replacement the practical importance of the foregoing remarks is that when these experiments were extended to the substances likely to be used in the construction of artificial joints [before the introduction of high molecular weight polyethylene (HMWP)] it was found that synovial fluid was incapable of acting as a lubricant. Thus a chrome-cobalt surface sliding on chrome-cobalt; stainless steel sliding on bare bone; and Perspex (Lucite or polymethylmethacrylate) sliding on bare bone; when lubricated with bovine synovial fluid all presented coefficients of friction in the region of 0.5 and squeaked under load. On the other hand stainless steel sliding on normal articular cartilage was well lubricated with synovial fluid (coefficient of friction in region of 0.05) and this combination therefore was not greatly inferior to articular cartilage sliding on articular cartilage (Fig. 1.5).

These observations therefore seemed to indicate that synovial fluid was a specific lubricant for articular cartilage and for nothing else. The specificity of a lubricant for the material of a surface is characteristic of boundary lubrication because it involves that quality known as 'oiliness'. This does not apply in hydrodynamic lubrication where oiliness in a lubricant is unnecessary: water or air can be used to lubricate hydrodynamically, provided that the geometry of the rotating surfaces, the area of the surfaces, the load to be carried and the speed of rotation are all known.

From these considerations the author decided in 1958 that the only chance of success in lubricating an artificial animal joint would be by using surfaces which were intrinsically slippery on each other; in other words, self-lubricating irrespective of whether tissue fluid were present or not. This led to trials of polytetrafluorethylene (Teflon,

PTFE), with spectacular early results. Unfortunately the poor wearing properties of pure PTFE, and the disastrous complications with PTFE 'filled' with material designed to enhance wear resistance, ended in PTFE being abandoned in 1961, after some 300 total hip operations had been performed with a number of different mechanical modifications. The PTFE era taught a number of very important lessons which might still have warnings for future development in this field and for this reason a brief review of selected experiences is cogent.

a) Particle Size and Tissue Reaction

It is now well known that PTFE in the hip joint produced voluminous masses of amorphous caseous material. This presumably is the proteinaceous material resulting from vast numbers of dead foreign-body giant cells. Particle size might be very important in the production of granulomatous material because PTFE particles were very large (often 300 μm) and their large size could prevent transport away from the site of production. The high rate of production of PTFE particles (rapidity of wear) in addition to the large size of the particles, might have been responsible for defeating the available transport system for removing the particles and the caseous debris. Therefore slow production (high wear resistance) and small size of abraded particles might be important features in reducing local accumulations of caseous material even if the production of wear particles may never be avoided.

Therefore it would seem possible, if wear has to be accepted as inevitable, that the ideal implant will produce very small particles. The factors which control the size of abraded particles of HMWP as yet are unknown but the particles produced in the (LFA) hip in the author's experience seem to be smaller than those produced in knee arthroplasties. This might suggest that the high loading of a small-diameter ball can prevent 'third body' abrasion, perhaps by burnishing the particles into the surface, perhaps by the tendency of the small-diameter head to 'bore' into the plastic and remain close fitting, rather than combining elements of rolling and sliding encouraged by the large-diameter spherical surfaces of the knee.

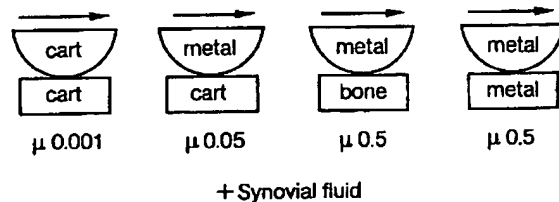


Fig. 1.5. Typical coefficients of friction with different pairs of substances in hip arthroplasty

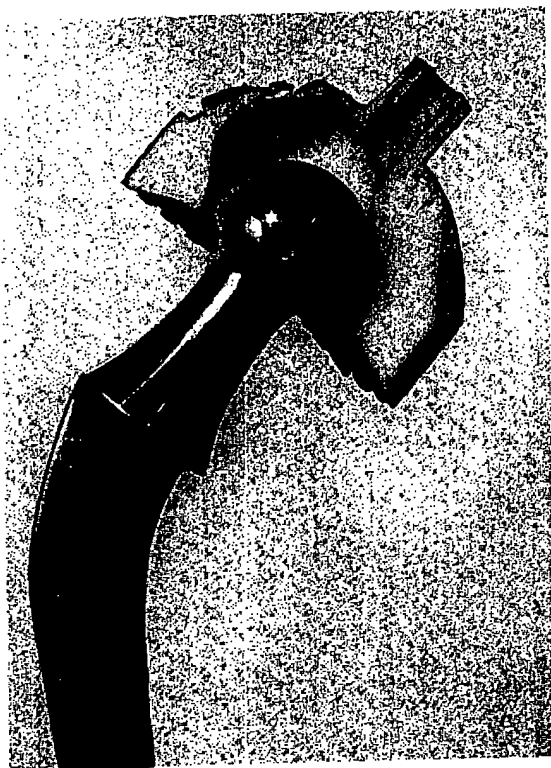


Fig. 1.6. Total wear-out of Teflon socket after 3 years. Note vertical direction of wear track

b) Direction of Socket Wear

The rapidity of wear of Teflon hip sockets enabled the direction of wear to be recognised in periods as short as 2 or 3 years (Fig. 1.6). When wear is very slight, as with HMWP, it is difficult to be sure of the precise direction of wear.

The frequency with which the direction of wear was vertically upwards, or even upwards and laterally, made Elson and Charnley (1968)⁽⁴⁾ recommend that in designing total hip replacements we should not count on the joint force being advantageously inclined at 10° medially but we should assume that the joint force acts as though it were directed vertically. This emphasizes, among many other matters, the importance of designing the hip socket to be totally enclosed inside the acetabulum.

c) Fillers to Enhance Wear Resistance

PTFE filled with glass fibre, or with a synthetic proprietary substance (Fluorosint-Polypenco)

showed enhanced wear resistance by a factor of 20 when lubricated with water in the laboratory. The surfaces of the plastics specimens also became highly polished in these laboratory experiments and the stainless steel counterface also remained in a high state of polish. In the human body however this type of filled PTFE behaved very badly. PTFE filled with glass fibre even after 1 year in the body developed a 'pasty' surface which could be scraped away with a blunt instrument. Fluorosint wore in the body just as rapidly as ordinary PTFE but the result was even worse, because the filler acted abrasively and lapped metal from the prosthetic head. The sockets retained a matt surface and never acquired the glazed surface that they did in the laboratory.

Ultra-High Molecular Weight Polyethylene

The introduction of HMWP by the author in 1962 as a material for socket surfaces in joint replacement necessitated a change of emphasis in lubrication theory as applied to artificial joints. The unique low coefficient of friction of PTFE could no longer be deployed and emphasis now had to be turned towards materials offering high resistance to wear and producing therefore a minimum of abraded detritus.

The coefficient of friction of HMWP is at least five times higher than that of PTFE, but its wear resistance in laboratory tests is 500–1000 times better. The very high wear resistance of HMWP now made acceptable the very high stresses on the plastics material produced by the small-diameter femoral head inseparable from concepts of low frictional torque. It thus became feasible to compensate for increased frictional resistance by designing for low frictional torque.

In this change of policy two unpredicted factors came to light which helped to offset the inferior coefficient of friction of HMWP compared with Teflon. In the first place HMWP is one of the plastics materials whose coefficient of friction becomes less under high stress; in the second place HMWP proved to be capable of a modest degree of boundary lubrication by synovial fluid. This latter property therefore made it an exception to

8 — Low Friction Principle

the author's statement in the early stages of this work that there were no substances available for joint replacement which could avail themselves of synovial fluid as a lubricant.

Pendulum Comparator

A method of attempting to compare the frictional torque of different designs of total hip implant is the pendulum 'comparator' illustrated in Fig. 1.7. This device, developed by the author at Wrightington, is not intended to measure absolute values of friction but merely to make broad, even qualitative, comparisons of the frictional torque offered by different designs of total hip replacement when compared against a 22-mm-diameter stainless steel sphere in a socket of HMWP. Like all methods of measuring frictional resistance these

tests are prone to erratic behaviour and it is impossible to make fine distinctions over the middle range of observed results; but for its main purpose, which is to reveal extremes of behaviour, it is valid.

The device consists of two separate pendulum systems each with a heavy metal bob of identical weight and swinging on ball bearings. Each pendulum carries a cylinder and piston connected by a flexible tube to a compressed air source to deliver a force of about 200 lb (90 kg) at each piston rod. The femoral head component of the device to be tested must be cut from its stem and attached, by brazing, to a stub to fit the piston rod.

The sockets to be tested are mounted in metal holders using acrylic cement (Fig. 1.8). The point corresponding to the centre of the hemispherical cavity of the socket must be at a prescribed distance above the base plate on which the holder lies. This distance is the height of the horizontal axis passing through the ball bearings of the pendulum. The metal mounts taking the hip sockets locate on three pins on the base of the comparator.

The comparison is made by drawing both pendula to their maximum amplitude where they are held by a trigger. The bobs are released simultaneously without applying load to the hip implants to be compared. The number of swings is counted until the pendula start to be out of phase but of course are still swinging vigorously (this will usually be about 8-10 half-cycles). This demonstrates that in the unloaded state there is no gross difference between the two sides. The bobs are again brought back to the starting triggers and air pressure is applied to the two implants to be compared. The bobs are released and the number of half-cycles on each side are counted until each pendulum stops.

The tests are performed with bovine synovial fluid as a lubricant. It is important that the implants should be freshly washed in soapy water which is then eliminated by an adequate period under a running tap. Thereafter care should be taken not to get grease from the fingers on to the test surfaces.

The apparatus can be criticised as being unphysiological in that a constant load is maintained on the to and the fro half-cycles. It is not possible to design otherwise because slight errors of centring, inevitable when parts of the instrument deflect under the load, could produce serious errors if the load were applied repeatedly in one direction and removed in the other. By maintaining a constant load the errors caused by the load assisting the swing in one direction are neutralised by the load impeding the swing in the other direction.

Another criticism is that the state of any fluid film which might exist must be best at the start and that any contribution of fluid lubrication must decline throughout a test. Against this it is main-

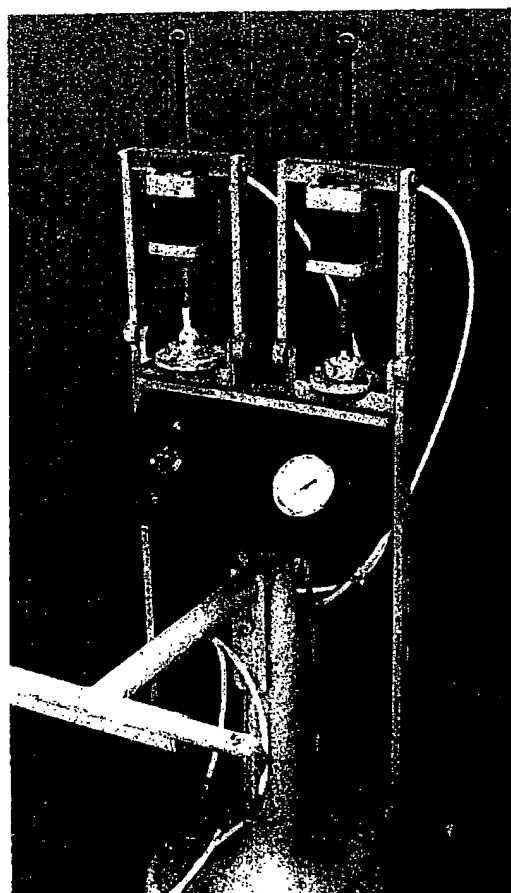


Fig. 1.7. Pendulum comparator

it is impos-
the middle
in purpose,
it is valid.

lum systems
it and swing-
s a cylinder
compressed
b (90 kg) at
nent of the
nd attached,

metal holders
corresponding
f the socket
base plate
ne height of
bearings of
hip sockets
rator.

pendula to
by a trigger.
ut applying
the number
t to be out
rously (this
emonstrates
s difference
ought back
plied to the
eleased and
unted until

ial fluid as
s should be
eliminated
Thereafter
the fingers

g unphys-
tained on
t possible
of centr-
ent deflect
errors if
direction
ng a con-
l assisting
ed by the
direction.
any fluid
the start
tion must
t is main-

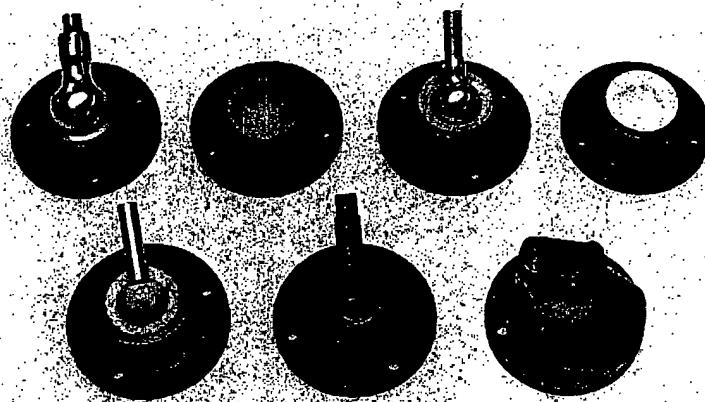


Fig. 1.8. Sockets mounted in holders to locate centre of rotation as near as possible to axis of the pendulum comparator

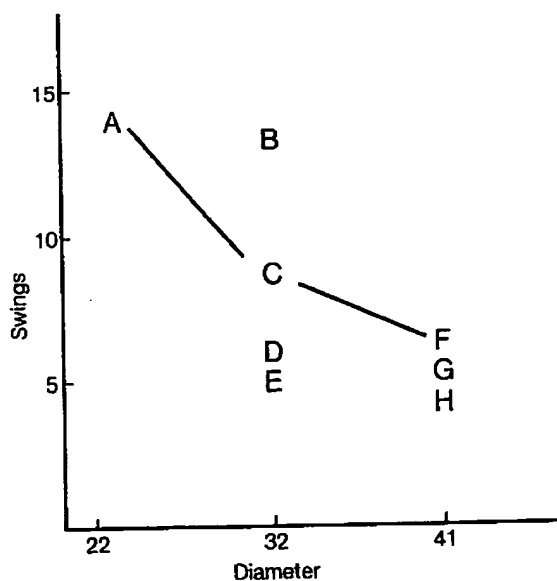


Fig. 1.9. A, C, F, represent different diameters of metal (stainless steel) ball on HMWP. The number of swings to stopping decreases as diameter increases: the opposite of what would be expected with fluid lubrication. Load 250 lb in all cases

D, polyester socket with 32-mm diameter chrome-cobalt head

E, ceramic (Al_2O_3) head 31-mm diameter on socket of same ceramic (Boutin)

B, ceramic (BioloX) head on HWMP socket

G, trunnion design (Weber) 42-mm polyester sphere

H, McKee-Farrar 41-mm chrome-cobalt head on socket of same

tained that, whatever may be the mechanism of lubrication, the comparison starts with all the joints being offered the same circumstances and the test reveals how different artificial joints react under these same starting conditions.

An important feature of the design is that the plane in which the ball oscillates is not unlike that during the weight-bearing phase of walking in the human body: the axis of rotation of the ball is at an angle to the central axis of the socket. To rotate the ball on the same axis as that of the socket would incur great variations in frictional torque depending on the fit of the ball in the socket: a large socket would give point contact with the head in the depth of the socket and therefore a very low frictional moment; a too-small socket would cause a 'cone-clutch' effect with binding of the head at the rim of the socket with very high frictional torque. An annular zone of contact halfway down the socket (as was recommended for the McKee-Farrar metal-to-metal implant) would give intermediate frictional torque. By oscillating in a plane perpendicular to the central axis of the socket, sensitivity to errors of fit of the ball in the socket is minimised because the length of the friction moment arm is the radius of the ball and is therefore constant.

Some typical results, the averages of many tests, all using lubrication with synovial fluid, are shown in Fig. 1.9. Points of special interest are as follows:

1. Metal/HMWP

The relationship between the number of swings and the diameter of the metal ball is well demonstrated in the sequence A (22 mm)—C (32 mm)—F (41 mm). If an important element of fluid-film lubrication were to be present one would expect that spheres with large diameters would make more swings than those with small diameters under

10 — Low Friction Principle

the same load because large-diameter spheres would generate lower fluid pressures than small spheres and large-diameter sockets would present a longer distance through which a viscous fluid would have to extrude under low pressures.

In practical tests the opposite is the case. The number of swings becomes fewer as the diameter increases (14 swings falling to 7 as the diameter increases from 22 mm to 41 mm) which is in favour of boundary lubrication theory.

2. Metal 32 mm/HMWP (C) compared with metal 32 mm/polyester (D)

The inferior performance of the polyester socket could be explained in several ways: (a) on boundary theory as indicating that the friction between metal and polyester was greater than with HMWP or (b) again on boundary theory that very thin (boundary) films of synovial fluid are not encouraged by polyester but are by HMWP. On hydrodynamic theory the inferior performance might be explained by the greater hardness of the polyester causing any fluid film that might be present to be immediately ruptured, whereas the compliance of the HMWP socket could permit a fluid film to spread and so reach a thinner layer before finally rupturing (elasto-hydrodynamic lubrication).

These explanations also apply to the behaviour of metal-to-metal prostheses (41-mm McKee chrome-cobalt) where three or four swings when dry is not improved at all (or only marginally) by adding synovial fluid.

3. Ceramic Spheres and Ceramic Socket [31-mm diameter (E) Boutin]

When first tested this combination performed well, being equal to a 35-mm metal sphere on HMWP i.e. C (7 swings). At this time the sphere and the socket both had a matt surface finish. After about 30 demonstrations in the pendulum comparator (perhaps 200 swings) the performance deteriorated to the present state (E) of only 4 swings. But worse than this, it now emits a high-pitched audible squeak. The appearance of the squeak and the deterioration of performance coincided with the rubbing surfaces acquiring some degree of polish.

4. Ceramic Sphere and HMWP Socket [(B) 30-mm diameter BioloX (Muller)]

This combination performs better than any other in the range equalling the performance of the 22-mm metal head. Because the BioloX head is 30 mm in diameter compared with the 22-mm metal head the coefficient of friction between this ceramic and HMWP must be less than that between metal and HMWP (The 30-mm BioloX head was an experimental head—the one used clinically is 32 mm in diameter.)

5. Trunnion Hip. Polyester sphere (42-mm diameter (G) Weber)

This unit performs badly in the pendulum comparator and is only slightly better than the 41-mm metal-to-metal McKee. It appears that very high frictional resistance between the large-diameter polyester sphere and metal socket prevents the small-diameter trunnion revealing its potential. It would seem that for a better performance the axis of the trunnion would have to be more horizontal if it is to share more of the flexion range of the hip joint.

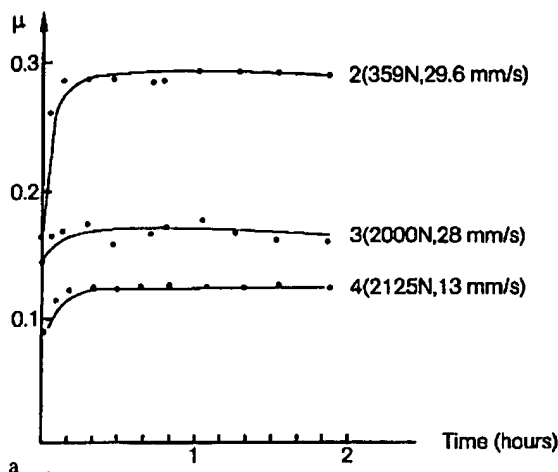
Coefficients of Friction in the Literature

The precise value of the coefficient of friction between any two sliding substances depends very much on the method used to make the measurement; for this reason the literature contains different values for the various combinations of materials which have been used in artificial joints.

An interesting feature of the pendulum comparator is how the performance has changed when giving monthly demonstrations with the same specimens over the years, though the relative values have been fairly constant. This would suggest that changes, possibly oxidative, can affect the rubbing surfaces over 10 years. When polished again the original values were restored.

Generally speaking a coefficient of friction between 0.05 and 0.10 would appear to the accepted value for metal on HMWP lubricated with synovial fluid (Simon and Radin)⁽⁵⁾. Compared with

Charnley hip joint unlubricated



Charnley hip joint lubricated with bovine synovial fluid

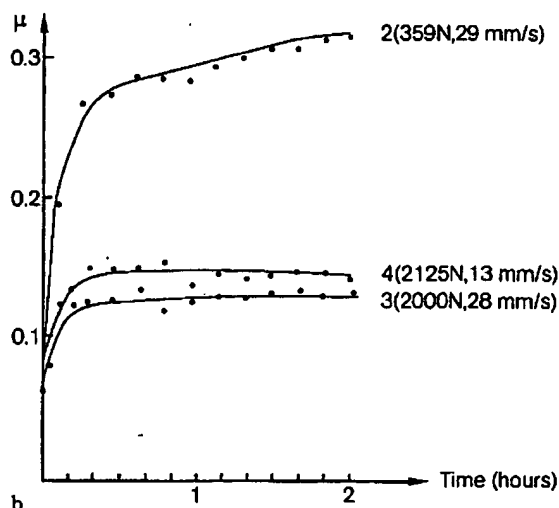


Fig. 1.10a, b. Leeds pendulum experiment with load varied throughout each cycle, by hydraulic mechanism, to simulate human gait. a Lubricated with bovine synovial fluid and b unlubricated. Note decrease in coefficient of friction as load increases. Fact that performance is not

different, lubricated or not lubricated with synovial fluid, despite loaded and unloaded half-cycles, strongly favours boundary lubrication mechanism as major contribution to lubrication

the coefficient of friction in normal animal joints, an order of magnitude lower, these are not particularly low values.

In a series of experiments carried out by the Bioengineering Group in Leeds⁽⁶⁾, using a different type of test, even higher frictional resistance was recorded with the 22-mm Charnley prosthesis on HMWP and the results were not materially reduced when lubricated with synovial fluid. This test was a pendulum experiment but the amplitude was maintained by an external power source. The load on the joint was varied by a hydraulically operated system which applied peak loads at the extremes of motion corresponding to 'heel-strike' and 'toe-off' in human gait. This physiological method of loading therefore would encourage fluid lubrication in the non-weight-bearing half-cycle, not possible in the author's very simple comparator. The frictional resistance was monitored at each swing. Fig. 1.10a, b reproduce their findings. It will be seen that within 10 min of starting a test, with or without synovial fluid, there was a rise in frictional resistance to 0.15 under a load of about 450 lb (2000 N). In this pendulum experiment it was notable that the coefficient of friction of the 22-mm head on HMWP, with or without synovial

fluid, was less under high loads than when lightly loaded. Thus under 80 lb (359 N) $\mu=0.3$ whereas at 450 lb approx. (2000 N) the coefficient of friction was half this value ($\mu=0.15$).

Is Low Frictional Torque Essential?

High frictional torque in a total hip under the full load of joint force in theory will help to loosen cement bonds. In theory also high frictional torque will reduce the amount of external work which the muscles can do by energy lost as heat in the bearing. Energy lost cannot be demonstrated in clinical practice, though in metal-to-metal bearings in laboratory conditions it can always be demonstrated that they offer frictional resistance to movement under heavy load and become warm.

On four or five occasions the author has performed bilateral total hip replacement comparing the 22-mm metal-to-plastic LFA in one hip with a 41-mm-diameter metal-to-metal McKee in the other and, with technically sound implants on both sides, no subjective difference between the two sides was volunteered by the patient nor was admitted on questioning. These patients did not

12 — Low Friction Principle

notice any feeling of weakness on the side of the metal-to-metal hip when ascending stairs compared with their sensations on the low-friction side.

The author suggests as one possible explanation that in the load-bearing phase of ascending stairs the metal-to-metal bearing might 'lock' and function as an arthrodesis. The same theory could conceivably apply even in bilateral metal-to-metal arthroplasties when ascending stairs: in this case the unloaded metal-to-metal hip will flex freely to reach the upper step, then it will progressively lock as load is transferred to it; the locked opposite hip which is taking load then progressively unlocks as load is removed. A considerable experience of arthrodesis of the hip indicates that in a unilateral arthrodesis the only defective phase in mounting stairs is that of reaching the upper step with the foot of the arthrodesed side. The act of putting weight on the arthrodesed hip and raising the body offers no problem and the sensation is indistinguishable from that of normal hip. In offering this explanation the locking is visualised as a gradual process, the change from free movement to seizure occupying perhaps 10° . Another 10° could easily be contributed by movement of pelvis and spine.

Another curious phenomenon, in the light of bad performance in the laboratory, when considering the behaviour of metal-to-metal total hip joints in clinical practice is that patients do not feel 'stick-slip' (which is the basis of a squeak) yet this is invariably detected when attempting to move a metal-to-metal total hip lubricated with synovial fluid under heavy load in the laboratory. In an experiment which the author has demonstrated many hundreds of times to visitors, a 41-mm McKee arthroplasty is wetted liberally with bovine synovial fluid and while the visitor is moving it slowly to and fro, manually through the medium of a lever, air pressure is suddenly applied to deliver 200 lb force. The metal-to-metal total hip locks instantaneously without a detectable period even as short as 0.5 s which might be occupied by the extrusion of the synovial fluid. Thereafter to move the metal-to-metal joint demands very considerable force, a grinding sound is audible and vibrations are detected through the lever.

One explanation could be that patients might not have a sensory mechanism in the bones of

the hip capable of transmitting this type of vibration to consciousness. It is always surprising to observe how patients with unoperated arthrotic hips which emit loud grating sounds seem to detect this by their ears just as do others in the same room; they do not seem to associate it with a special sensation coinciding with the grating sound.

Yet another explanation might be that in the living body, metal-to-metal joints might be lubricated with a type of synovial fluid which cannot be imitated by bovine synovial fluid in the laboratory. In other words, a proteinaceous substance in the living environment might become conjugated with the metallic elements in the sliding surfaces in a way not reproducible in the non-living circumstances of the laboratory.

As regards the question whether low frictional torque in a total hip replacement plays a significant role in preventing loosening of the cemented components, an argument cited against this is derived from experimental work on sockets cemented into the cadaveric acetabulum (Anderson et al) ⁽⁷⁾. In this study it was found that torsional moments needed to loosen cemented sockets were from 4 to more than 20 times greater than any frictional moment capable of being transmitted from a prosthetic femoral head. While there can be no disputing these laboratory findings this type of experiment overlooks the fact that if demarcation of a cemented socket from the adjacent cancellous bone is present (from the biological reaction of bone to microscopic movement of cement in contact with it over a period of years) the avoidance of high frictional torque might permit such a socket to function for many more years than would be the case if high frictional torque were present. The loading of a cemented socket in the relatively constant direction of the joint force is almost certainly the main cause of socket loosening; but add to this high frictional torque in the later stages of this process and then clinical failure is accelerated.

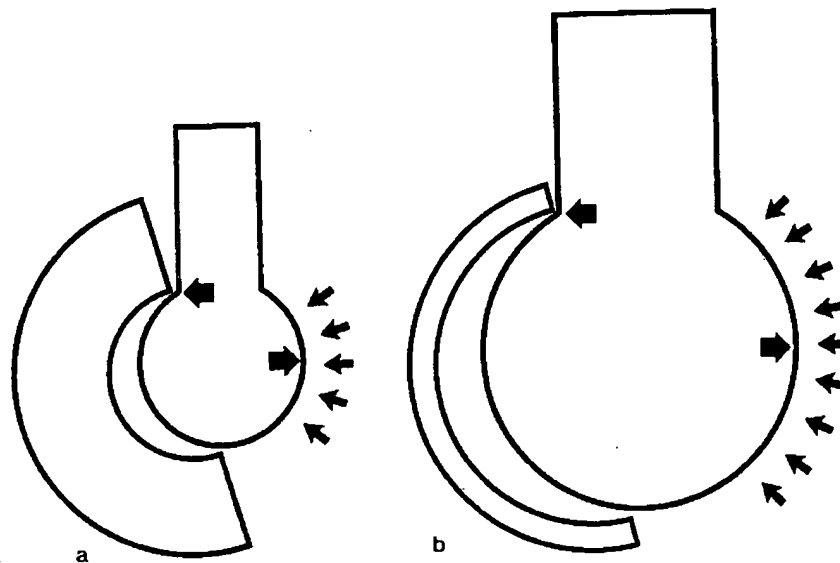


Fig. 1.11a, b. Demonstrating magnitude of forces reacting on cement bonds, both of socket and of femoral prosthesis, at moment of traumatically exceeding designed range. **a** In case of small-diameter head, force resisting dilation of capsule is small; consequently equal and opposite force reacting against socket also is small; but thick-

walled socket preserves maximum external surface area to resist shearing force imposed on it. **b** In case of large-diameter head, force resisting dilation of capsule is great; consequently equal and opposite force reacting against socket also is great; but external surface area of socket resisting shearing forces is identical with that in case **a**

Size of Femoral Head and the 'Safety Valve' of the Hip

The small-diameter femoral head demanded by the theory of low frictional torque originally caused some anxiety because obviously it could be prone to post-operative dislocation. Once the factors controlling stability had been clearly defined (Chap. 19) an advantageous side-effect was recognized in the possibility that transient subluxation could occur during severe trauma. By transient subluxation we mean momentary and incomplete escape of the femoral head from the socket when the joint is forcibly and traumatically made to exceed the designed range. Incomplete escape of the head is then followed instantaneously by return of the head to its normal position when the overstretched limb returns within its proper range.

In the case of the 41-mm McKee prosthesis a common observation at secondary interventions is a bright spot on the neck corresponding with a point of impingement on the rim of the socket. McKee himself frequently attributed loosening of one or other of the components to the patient

sustaining trauma as the result of a fall. In our experience with the 22-mm head we cannot recall a single case where loosening of cement clearly followed trauma. On the contrary it is a common experience to have elderly patients reporting back to hospital after falls, proved by demonstrating cuts or bruises on their knees.

The author's explanation is that if a 41-mm-diameter McKee head is at the critical point of starting to be levered out of the socket, as the range is being forced beyond the point of impingement of the neck, the large head will have to stretch the capsule (or the fibrous reconstruction of the excised capsule) to produce a much greater volumetric distension of the capsule than would be the case with a small head (Fig. 1.11). The force needed to do this would react on the stem of the femoral prosthesis and possibly also on the socket.

Thickness of Socket Wall

The concept of low frictional torque in total hip replacement using a prosthetic head of minimum

14 — Low Friction Principle

diameter and a socket of maximum external diameter, was prompted originally by the idea that a major difference in diameters would render cement in the acetabulum unnecessary. It was also recognized that a plastics socket with a thick wall would diffuse the load from a small ball more evenly over the socket-cement-bone interface than would a large ball acting through a thin-walled socket. The more uniformly loaded is the cement layer in the acetabulum the less likely is it to produce 'high spots' on the cement-bone interface which might precipitate minute, localised movement between cement and bone eventually producing a histiocyte reaction and bone cavitation with the start of loosening (Chap. 4).

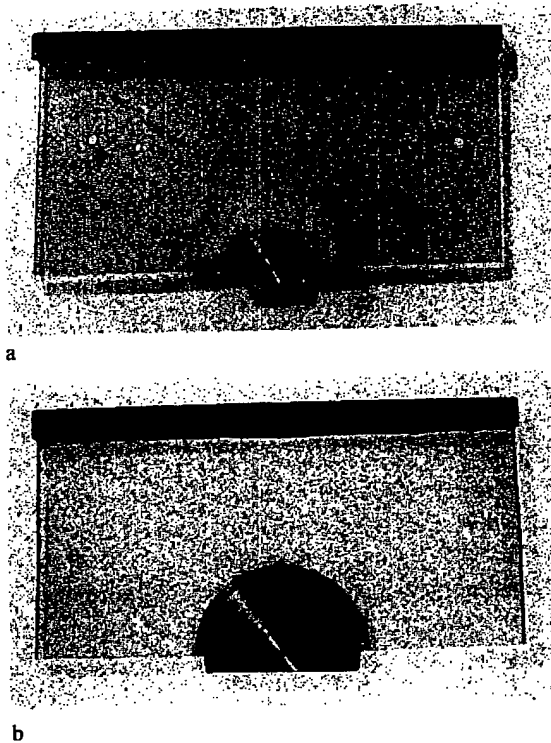


Fig. 1.12a, b. Photoelastic models to illustrate effect of thickness of socket on distribution of load. Sheet of photo-sensitive plastics material represents the bone of the acetabulum. It is important that the external surface of HMWP socket should be *adherent* to substance representing bone (simulating the socket-cement-bone entity). Grooved metal bar cemented to top of sheet of photo-elastic material helps to diffuse load from test apparatus equally over the specimen, so reducing 'high spots' to a minimum.

a 22.25 mm diameter metal cylinder – 56 mm external diameter HMWP 'socket'; b 50 mm diameter metal cylinder – 56 mm external diameter HMWP 'socket'

With the general trend (by 1977) for designs of metal-to-plastics total hip to be moving towards the smaller ranges of femoral head (32, 28 and 25 mm) it seemed unlikely to be profitable to examine further the effects of small differences in diameter, but in 1978 the 'double-cup' design of hip arthroplasty has emerged, using a metal sphere up to 50 mm in external diameter with a socket only about 3 mm thick (Appendix B). Because the 14-year studies of the LFA (Chap. 6) have shown that socket loosening is going to be the most likely cause of very late failure, even with a small-diameter head and a thick socket, there is a possibility that a very large head and a very thin socket could be a retrograde step. This prompted the author with engineering colleagues¹⁾ to undertake photo-elastic studies to illustrate load distribution at socket-cement-bone interfaces in relation to the thickness of the wall of a socket.

The photo-elastic demonstration used two models where the bone of the pelvis was represented by a sheet of Araldite CT 200 and the metal spheres by cylindrical steel discs (Fig. 1.12). The large metal disc measured 50 mm in external diameter and the small disc, 22.25 mm. The HMWP sockets were represented by semicircular discs both 56 mm in external diameter cemented into semicircular concavities of the same diameter in the Araldite. It was imperative to have a cemented joint between the polyethylene and the Araldite just as in the living situation.

The concavities of the polyethylene discs originally corresponded to the diameters of the metal cylinders but after cementing in position were too tight, and scraping was necessary to achieve a fit which gave the same sensation of free movement present in the hemispherical specimens used in surgery.

When viewed through a circular polariscope the resulting fringe patterns for an applied load of 325 lb are given in Fig. 1.13 for the small ball and for the large ball. The fringe orders are proportional to the principal stress in the Araldite. For the small ball the maximum fringe order is estimated to be 2.5 and stresses are more or less evenly distributed over the 180° interface between the socket and the Araldite. For the large ball the maximum fringe order is estimated to be 3.5 and stresses are concentrated over the central 90° of the interface between the socket and the Araldite.

¹⁾ Dr. R. Kitching and Dr. R.D. McLeish, Department of Mechanical Engineering, University of Manchester Institute of Science and Technology.

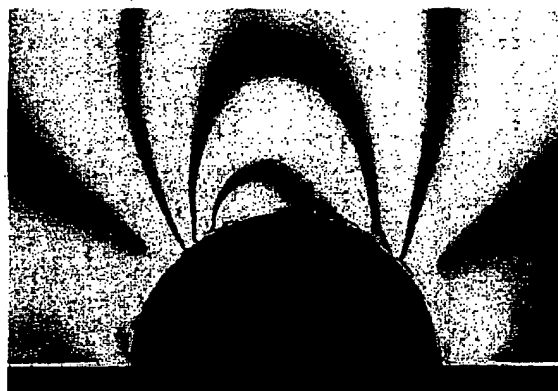
The maximum stresses in the plastic representing the bone of the acetabulum are (3.5/2.5) (1.4 times) higher with the thin socket than with the thick socket and these higher stresses are distributed over only about one-half of the area of cement-bone interface. The lower stresses produced by the thick socket are distributed more or less evenly over the whole area of the cement-bone interface. If the fit between the large ball and the thin socket were to be less good than in this experiment the zone of high stress would be more localised and higher in magnitude. With the thick socket on the other hand the stress will continue to be more evenly distributed on the cement-bone interfaces even if the ball were to be considerably smaller than a perfect fit.

From the point of view of the surgical manufacturer it is always difficult to be sure to what extent a socket of a plastics material made to close tolerances will hold these dimensions when internal stresses, etc. are relieved. It would be disastrous to use a socket which is too tight on a large head, because this could act as a powerful 'brake' and never have an opportunity to wear loose. Also to make different sockets and heads interchangeable, there will always be a tendency to deliver sockets erring on the side of looseness on a large head.

To this must also be added the fact that plastics materials have a much higher coefficient of thermal expansion than metal. Ideally a manufacturer should supply a socket which is too tight at room temperature so that it will be a perfect fit when at body temperature, but it is preferable to err on the side of a loose fit and hope that the head will adapt perfectly by a combination of wear and plastic flow.



a



b

Fig. 1.13a, b. *Top illustration* shows the thick socket under load from small-diameter metal prosthetic head. Fringes are distributed evenly over whole surface of socket. *Bottom illustration* shows thin socket and large-diameter metal prosthetic head under same load as above. Stresses are now concentrated over only a 90° quadrant of socket surface and are nearly 1.5× higher than in case above. Under polarised light and both under load of 325 lb: a Two fringes on specimen (a) of Fig. 1.12; b three fringes on specimen (b) of Fig. 1.12

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.